



## Agilent 1200 Series



**GLP**

**ISO 9001**

**GMP**

**ISO GUIDE 25**

**cGMP**

**EN 45001**

**GLP**

## Qualification Workbook



**Agilent Technologies**

# Notices

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## Safety Notices

### CAUTION

A **CAUTION** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in damage to the product or loss of important data. Do not proceed beyond a **CAUTION** notice until the indicated conditions are fully understood and met.

### WARNING

A **WARNING** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in personal injury or death. Do not proceed beyond a **WARNING** notice until the indicated conditions are fully understood and met.

## About this Book...

This Qualification Workbook for the AGILENT TECHNOLOGIES 1200 Series systems and modules for LC contains documents of the 4 phases of the entire instrument life in a user's laboratory:

- Design Qualification (DQ),
- Installation Qualification (IQ),
- Operational Qualification (OQ),
- Performance Qualification (PQ).

The book will help to demonstrate, e.g. in case of an audit or inspection, that the instrument is qualified independent of its age. For this purpose the workbook needs to be updated regularly.

The documents in the chapter Design Qualification (DQ) Phase demonstrate the qualification of the vendor and the instrument's functional and performance specifications.

Because system qualification is not a one-time event Agilent Technologies has set-up processes to enable qualification during the entire product life. Therefore the workbook contains examples for qualification documents of the other phases of the instrument's lifetime. The user must replace them with the originals at appropriate time. The user should feel free to add further documents whenever he/she thinks this is appropriate(1).

The AGILENT TECHNOLOGIES 1200 Series Qualification Workbook contains documents for a 1200 Series system containing at least one of the following 1200 Series modules.

### NOTE

Please printout this document and put it in a binder. You can add your own material to this Qualification Workbook.

### Module

- isocratic pump
- binary pump
- binary pump SL
- capillary pump
- nanoflow pump
- quaternary pump

- vacuum degasser
- micro vacuum degasser
- manual injector
- autosampler
- high performance autosampler
- high performance autosampler SL
- thermostatted autosampler
- thermostatted high performance autosampler
- thermostatted column compartment
- thermostatted column compartment SL
- variable wavelength detector
- variable wavelength detector SL
- diode array detector
- diode array detector SL
- fluorescence detector
- LC/MSD module
- handheld controller Instant Pilot
- AGILENT TECHNOLOGIES ChemStation for LC Systems

## **1 Overview**

## **2 Design Qualification (DQ) Phase**

## **3 Installation Qualification (IQ) Phase**

## **4 Operational Qualification (OQ) Phase**

## **5 Performance Qualification (PQ) Phase**

## 1 Overview

### Introduction

- Design Qualification (DQ) Phase
- Installation Qualification (IQ) Phase
- Operational Qualification (OQ) Phase
- Performance Qualification (PQ) Phase

Agilent's line of proven qualification products and services

## 2 Design Qualification (DQ) Phase

Iso 90001: Valid June 2006 Certificate

### Pump Specifications

- G1310A Isocratic Pump
- G1311A Quaternary Pump
- G1312A Binary Pump
- G1312B Binary Pump SL
- G1361A Preparative Pump
- G1376A Capillary Pump
- G2226A Nano Pump

### Injection Systems Specifications

- G1329A Autosampler 100 µl metering head
- G1329A Autosampler 900 µl metering head
- G2260A Preparative Autosampler
- G1367B High Performance Autosampler and  
G1367C High Performance Autosampler SL
- G1377A Micro Well plate Sampler

### Detectors Specifications

- G1314B Variable Wavelength Detector and  
G1314C Variable Wavelength Detector SL
- G1315B Diode Array Detector
- G1365B Multiple Wavelength Detector

## Contents

- G1315C Diode Array Detector SL
- G1365C Multible Wavelength Detector SL
- G1362A Refractive Index Detector

### Fraction Collectors Specifications

- G1364B Fraction Collector preparative scale
- G1364C ANALYTICAL SCALE Fraction Collector
- G1364D Micro Collector/Spotter

### Valves Specifications

- G1157A Agilent 1200 Series 2 position / 10 port valve
- G1158A Agilent 1200 Series 2 position / 6 port valve
- G1159A Agilent 1200 Series 6 position selection valve
- G1160A Agilent 1200 Series 12 position/ 13 port selection valve
- G1162A Agilent 1200 Series 2 position/ 6 port micro valve
- G1163A Agilent 1200 Series 2 position/ 10 port micro valve

### Miscellaneous Specifications

- G1322A Vacuum Degasser
- G1379B Micro Vacuum Degasser
- G1316A Thermostatted Column Compartment
- G1316B Thermostatted Column Compartment
- G1330A Autosampler Thermostat

### Agilent ChemStation Specifications

### Agilent ChemStation Plus Specifications

### Compliance

### Customer contributed documents

## 3 Installation Qualification (IQ) Phase

### Side Preparation Specification Checklist

- Agilent 1200 Series Liquid Chromatograph Hardware Site Preparation Specification
- Agilent 1200 Series LC/MSD G1956A/B, G2908BA, G3218AA, G3218BA Site Preparation Specification

Agilent ChemStation Software Modules G2070BA, G2071BA, G2072BA,  
G2170BA, G2171BA, G2180BA Software Site Preparation Specification  
B.02.01

Agilent ChemStation Software Modules G2070BA, G2071BA, G2072BA,  
G2073BA, G2170BA, G2171BA, G2180BA, G2090BA, G2710BA, G1601BA,  
G2201BA B.02.01 Upgrade Site Preparation Checklist

#### Installation Qualification

Agilent 1200 Series Liquid Chromatograph Hardware and Software Installation  
Checklist

Agilent LC and CE ChemStation Software G2170BA, G2171BA, G2175BA,  
G2180BA, G2185BA, G211601BA, G2172BA, G2205BA Software Installation  
Checklist B.02.0x

#### Familiarization Checklist

Agilent 1200 Series Liquid Chromatograph Familiarization Checklist

Agilent 1200 Series Liquid Chromatograph Scope of Work Installation and  
Familiarization

#### Declaration of Conformity and System Validation

Declaration of Conformity According to ISO/IEC Guide 22 and CEN/CENELEC  
EN 45014

Declaration of Conformity to manufacturing Specifications

#### ChemStation Declaration of System Validation

#### ChemStation Installation Verification Report

#### Customer contributed documents

### **4 Operational Qualification (OQ) Phase**

#### OQ/PV Protocols

#### Agilent ChemStation Verification Test Report

#### Certificates showing traceability of:

Standard: Caffeine Kit

Holmium Oxid Glass Filter (Type Hoya HY-1)

#### Customer contributed material

**5 Performance Qualification (PQ) Phase**

Preventive Maintenance Checklist

Agilent 1200 Series Liquid Chromatograph Preventive Maintenance Checklist

Agilent 1200 Series Liquid Chromatograph Scope of Work Preventive  
Maintenance

Agilent 1100/1200 Series LC/MSD Quad Major Preventive Maintenance  
Checklist

Agilent 1100/1200 Series LC/MSD Quad Major Interim Preventive  
Maintenance Checklist

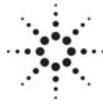
System performance and noise

Customer contributed material

## System Description

This book is dedicated to the HPLC system below.

[illegible]



**Agilent Technologies**    Agilent 1200 SERIES HPLC SYSTEM CHANGE CONTROL DOCUMENT

System #	Location

Date	Details of Change	Reason for Change	Change made By	Details of Qualification	Reason for Qualification	Results of Qualification	Approved for Use By

Change Control Document Number [       ]



# 1 Overview

## Introduction

Agilent's line of proven qualification products and services

This chapter gives you a short introduction to this workbook



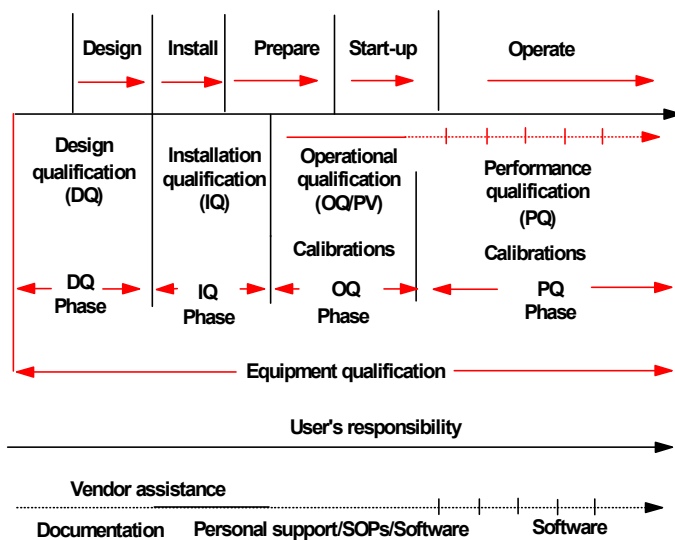
## Introduction

Proper functioning and performance of equipment plays a major role in obtaining consistency, reliability and accuracy of analytical data. Therefore, equipment qualification should be part of any good analytical practice (1).

The term qualification, as previously applied for qualification of computer systems by the U.S. Pharmaceutical Manufacturers Association, has been broken down by Freeman and coworkers (2) into four areas, which describe the entire life of the equipment:

- Design qualification (DQ) for setting functional and performance specifications (operational specifications),
- Installation qualification (IQ) for performing and documenting the installation in the selected user environment,
- Operational qualification (OQ) for testing the equipment in the selected user environment to ensure that it meets the previously defined functional and performance specifications,
- Performance qualification (PQ) for testing that the system consistently performs as intended for the selected application

## Qualifications Time Line



**Figure 1** Qualifications time line

## Design Qualification (DQ) Phase

### Definition and frequency

Design qualification defines the functional and operational specifications of the equipment and details the conscious decisions in the selection of the supplier (3). The DQ phase is finished with the purchase of the equipment.

### Who performs design qualification

The user always should perform DQ. The instrument's functional and performance specifications from the vendor can be used as a source for information



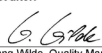

### The AGILENT TECHNOLOGIES 1200 Series concept

All Agilent Technologies liquid chromatography systems are developed and produced in compliance with the International Organization for Standardization quality standards ISO 9001 (refer to ISO 9001 certificate in chapter Design Qualification (DQ) Phase), and in accordance with the specifications of AGILENT TECHNOLOGIES' Life Science and Chemical Analysis Group life-cycle document.

The life-cycle concept for product development and validation is common in many engineering and manufacturing fields and was proposed by the American National Standards Institute (ANSI), the Pharmaceutical Manufacturers Association (PMA), the US Environmental Protection Agency (EPA) and the International Organization for Standardization (ISO). Software products are in addition developed and produced in compliance with ISO 9000-3 as a guide (refer to its certificate in chapter Design Qualification (DQ) Phase).

Prior to shipment to the customer, each AGILENT TECHNOLOGIES 1200 Series hardware module is verified in the factory and is shipped together with a

- Declaration of Conformity, figure 2, which declares that the instrument has successfully passed all production quality tests
- Declaration of Conformity according to ISO/IEC Guide 22 and EN 45014. This document states that the product conforms to the safety and electromagnetic conductivity specifications and carries the CE marking.


 <b>Agilent Technologies</b>	<b>DECLARATION OF CONFORMITY</b> <small>According to ISO/IEC Guide 22 and CEN/CENELEC EN 45014</small>																																														
<p><b>Manufacturer's Name:</b> Agilent Technologies International sari  <b>Manufacturer's Address:</b> Rue de la Gare 29  <b>Supplier's Address:</b> CH – 1110 Morges  Switzerland</p>																																															
<p><b>Declares under sole responsibility that the product as originally delivered</b></p>																																															
<p><b>Product Name:</b> 1200 Series Isocratic Pump, 1200 Series Quaternary Pump</p>																																															
<p><b>Model Number:</b> G1310A, G1311A</p>																																															
<p><b>Product Options:</b> This declaration covers all options of the above products</p>																																															
<p><b>complies with the essential requirements of the following applicable European Directives, and carries the CE marking accordingly:</b></p> <p style="text-align: center; font-size: small;">Low Voltage Directive 73/23/EEC, amended by 93/68/EEC  EMC Directive 89/336/EEC, amended by 93/68/EEC</p>																																															
<p><b>and conforms with the following product standards:</b></p> <table style="width: 100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th style="text-align: left;">EMC</th> <th style="text-align: left;">Standard</th> <th style="text-align: left;">Limit</th> </tr> </thead> <tbody> <tr> <td></td> <td>IEC 61326-1:1997+A1:1998 / EN 61326-1:1997+A1:1998</td> <td></td> </tr> <tr> <td></td> <td>CISPR 11:1997 / EN 55011:1998</td> <td>Group 1 Class B</td> </tr> <tr> <td></td> <td>IEC 61000-3-2:1998 / EN 61000-3-2:1995+A1:1998</td> <td>Group 1 Class A <sup>(1)</sup></td> </tr> <tr> <td></td> <td>IEC 61000-3-3:1994 / EN 61000-3-3:1995</td> <td></td> </tr> <tr> <td></td> <td>IEC 61000-4-2:1999 / EN 61000-4-2:1995+A1:1998</td> <td>4kV CD, 8kV AD</td> </tr> <tr> <td></td> <td>IEC 61000-4-3:1999 / EN 61000-4-3:1995+A1:1998</td> <td>3 V/m, 80-1000 MHz</td> </tr> <tr> <td></td> <td>IEC 61000-4-4:1995 / EN 61000-4-4:1995</td> <td>0.5kV signal lines, 1kV power lines</td> </tr> <tr> <td></td> <td>IEC 61000-4-5:1995 / EN 61000-4-5:1995</td> <td>0.5 kV line-line, 1 kV line-ground</td> </tr> <tr> <td></td> <td>IEC 61000-4-6:1996 / EN 61000-4-6:1996</td> <td>3V, 0.15-80 MHz</td> </tr> <tr> <td></td> <td>IEC 61000-4-11:1994 / EN 61000-4-11:1994</td> <td>1 cycle (20ms), 100%</td> </tr> <tr> <td></td> <td colspan="2">Australia/New Zealand: AS/NZS 2064.1</td> </tr> <tr> <td></td> <td colspan="2">Canada ICES / NMB-001:1998</td> </tr> <tr> <td></td> <td colspan="2">The product was tested in a typical configuration with Agilent Technologies test systems.</td> </tr> <tr> <td></td> <td colspan="2"><sup>(2)</sup> 1200 Series module with LAN Communication Interface attached.</td> </tr> </tbody> </table>			EMC	Standard	Limit		IEC 61326-1:1997+A1:1998 / EN 61326-1:1997+A1:1998			CISPR 11:1997 / EN 55011:1998	Group 1 Class B		IEC 61000-3-2:1998 / EN 61000-3-2:1995+A1:1998	Group 1 Class A <sup>(1)</sup>		IEC 61000-3-3:1994 / EN 61000-3-3:1995			IEC 61000-4-2:1999 / EN 61000-4-2:1995+A1:1998	4kV CD, 8kV AD		IEC 61000-4-3:1999 / EN 61000-4-3:1995+A1:1998	3 V/m, 80-1000 MHz		IEC 61000-4-4:1995 / EN 61000-4-4:1995	0.5kV signal lines, 1kV power lines		IEC 61000-4-5:1995 / EN 61000-4-5:1995	0.5 kV line-line, 1 kV line-ground		IEC 61000-4-6:1996 / EN 61000-4-6:1996	3V, 0.15-80 MHz		IEC 61000-4-11:1994 / EN 61000-4-11:1994	1 cycle (20ms), 100%		Australia/New Zealand: AS/NZS 2064.1			Canada ICES / NMB-001:1998			The product was tested in a typical configuration with Agilent Technologies test systems.			<sup>(2)</sup> 1200 Series module with LAN Communication Interface attached.	
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<p><b>Supplementary Information:</b></p> <p style="font-size: x-small;">This ISM device complies with Canadian ICES-001. Cet appareil ISM est conforme à la norme NMB-001 du Canada.</p>																																															
<p><b>This DoC applies to above-listed products placed on the EU market after:</b></p>																																															
<div style="display: flex; justify-content: space-between;"> <div style="width: 40%;"> <p>December 19, 2005 Date</p> </div> <div style="width: 50%; text-align: right;">   Wolfgang Wilde, Quality Manager </div> </div>																																															
<p style="text-align: center;">For further information, please contact your local Agilent Technologies sales office, agent or distributor,  or Agilent Technologies Deutschland GmbH, Herrenberger Straße 130, D 71034 Böblingen, Germany.</p>																																															
<p>Revision: A</p>		<p>Document No. G1311-90510</p> 																																													

**Figure 2** Declaration of Conformity

Every AGILENT TECHNOLOGIES ChemStation is shipped with the

- Declaration of System Validation, figure 3. The document declares that the AGILENT TECHNOLOGIES ChemStation software was developed, tested and successfully validated according to the Software Life Cycles, and Quality Manuals followed by the solution units of the AGILENT TECHNOLOGIES Life Science and Chemical Analysis Group.

Although the declarations belong to the DO phase we have added an example copy of each to the chapter Installation Qualification (IQ) Phase, because the installing customer engineer will attach the originals to the Installation Qualification Protocol to demonstrate that he/she has installed factory verified equipment.

**Agilent Technologies**

**Declaration of System Validation**

We herewith inform you that the software product/system

Product Name	Product Number	Revision Number
ChemStation for GC	G2070BA, G2071BA, G2075BA, G2090BA	B.02.0x (where x ranges from 0 to 9)
ChemStation for LC	G2170BA, 2171BA, G2175BA, G2180BA, G2185BA, G2190BA	B.02.0x (where x ranges from 0 to 9)
ChemStation for A/D	G2072BA, G2073BA, G2077BA	B.02.0x (where x ranges from 0 to 9)
ChemStation for CE	G1601BA, G2172BA, G2205BA	B.02.0x (where x ranges from 0 to 9)
ChemStation for CE/MS	G2201BA	B.02.0x (where x ranges from 0 to 9)
ChemStation for LC/MS	G2710BA, G2715BA, G2720BA, G2730BA, G2731AA	B.02.0x (where x ranges from 0 to 9)
Software Revision updates	G1050B	Not applicable

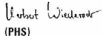
was developed according to the quality process and software life cycle followed by the Life Sciences and Chemical Analysis divisions of Agilent Technologies. Life cycle check-point details were reviewed and approved by management. The product was found to meet its functional and performance specifications, and release criteria at release to shipment.


In order to fulfill the validation requirements of the users of this product according to current regulations and quality standards including, but not limited to, 21 CFR 210 (Good Manufacturing Practice for Drugs), 21 CFR 211 (current Good Manufacturing Practice for finished pharmaceuticals), 21 CFR 58 (Good Laboratory Practice), Agilent Technologies will make the source code and the documents referenced on page 2 of this declaration available to an authorized governmental or regulatory agency for inspection at its Pharmaceutical Solutions Unit, Waldfbronn, Germany (terms and conditions to be negotiated). Agilent Technologies will maintain possession of all documents and their reproductions and may require a confidential disclosure agreement to be provided by those requiring access to these documents.

Date:


February 2006

Engineering manager:

  
(PHS)

  
(CAS)

Quality manager:

  
(PHS)


  
(CAS)

Figure 3 Declaration of System Validation

Contribution of the Qualification Workbook

The chapter Design Qualification (DQ) phase contains documents on the qualification of the vendor and on the design qualification of the equipment. The user has to add further documents, e.g. detailing his conscious decisions in the selection of the supplier (1).

## Installation Qualification (IQ) Phase

### Definition and frequency

Installation qualification (IQ) establishes that the instrument is received as designed and specified, that it is properly installed in the selected environment, and that this environment is suitable for the operation of the instrument (3). The IQ phase is finished after the successful installation and the signing of the Installation Qualification Protocols by a trained representative of AGILENT TECHNOLOGIES and the customer.

### Who performs installation qualification?

IQ for large, complex instruments as liquid chromatographs should be performed by vendors. Only for small, low-cost instruments such as pH meters IQ can be performed by users.

### The AGILENT TECHNOLOGIES 1200 Series concept

The process is broken into

- Installation Qualification for Hardware

The installation follows a documented procedure. The equipment is checked for completeness and proper function after installation. AGILENT TECHNOLOGIES provides field proven protocols for Installation Qualification (IQ) which is followed, filled out and signed by a trained AGILENT TECHNOLOGIES representative during an installation. For a system that consists of several modules, IQ includes an injection and qualitative evaluation of the isocratic standard sample, which verifies the correct installation of all fluid and electrical tubing and cables.

- Installation Qualification for software and computer systems

The installation of software follows a documented procedure. Installation of software on a computer is checked for integrity. AGILENT TECHNOLOGIES provides installation qualification software for integrity check of the AGILENT TECHNOLOGIES ChemStation software, which is executed during installation.

### **Contribution of the Qualification Workbook**

The chapter Installation Qualification (IQ) Phase contains documents showing current installation qualification. The chapter must be updated by the user if a change happens to the system, e.g. when a new software revision is installed.

## **Operational Qualification (OQ) Phase**

### **Definition and frequency**

Operational qualification is the process of demonstrating that an instrument will function according to the operational specification in the selected environment (3). This process is called

Operational Qualification (OQ) in the Pharmaceutical/FDA environment and Performance Verification (PV) in the ISO/EN/Accreditation environment.

The tests have to be performed by the user on a regular basis. In general, users should select time intervals between the tests so the probability is high that all parameters still are within the operational specifications. Typically the respective tests should be performed:

- After installation,
- After a change to the system,
- After a major repair
- At defined time intervals. For AGILENT TECHNOLOGIESLC equipment the interval is typically one year.

### **Who performs operational qualification/performance verification?**

OQ can be performed either by vendors or users. Business or economics needs rather than technical concerns determine this choice. The decision mainly depends on the resources available at the user's site and on the vendor's capability to offer the service with high quality.

## The AGILENT TECHNOLOGIES 1200 Series concept

**Automated OQ/PV of equipment hardware and complete systems.** OQ/PV tests include rigorous performance testing of the instruments on-site. A report is generated with acceptance criteria, actual results and pass/fail comments that are acceptable to investigators/auditors.

**Automated OQ/PV of AGILENT TECHNOLOGIES ChemStation** The correct function of the AGILENT TECHNOLOGIES ChemStation should be checked prior to routine use, after module and system updates, for example, after changing a processor board on the computer or after software updates. The AGILENT TECHNOLOGIES ChemStation's OQ/PV software checks key functions of the software, such as data acquisition, peak integration, quantitation, file storage and retrieval. It checks any influence from the environment, e.g., motors, high frequency lamps, on data transfer.

Results generated during the AGILENT TECHNOLOGIES ChemStation verification are compared to known, prerecorded values. The same principle may be applied to data files and methods generated by the user. A report is printed that is acceptable to investigators/auditors.

### Contribution of the Qualification Workbook

The chapter Operational Qualification (OQ) phase contains examples of documents as the OQ/PV reports on the AGILENT TECHNOLOGIES 1200 modules and the AGILENT TECHNOLOGIES ChemStation, which demonstrate that the equipment functions according to operational specifications.

The documents must be updated by the user whenever tests have been performed.

## Performance Qualification (PQ) Phase

### Definition and frequency

Performance qualification is the process of demonstrating that an instrument consistently performs according to a specification appropriate for its routine use (3).

The test frequency - every day, every month or whenever the instrument is used - is much higher than for OQ. It depends not only on the stability of the equipment but on everything in the system that may contribute to the analytical results, e.g. column and detector lamp. The test criteria and frequency should be determined during the development and validation of the AGILENT TECHNOLOGIES LSC method.

Another difference is that PQ always should be performed under conditions that are the same or similar to routine sample analysis.

### **Who does performance qualification?**

PQ always should be performed by users because it is application specific, and vendors may be unfamiliar with the applications.

### **The AGILENT TECHNOLOGIES 1200 Series concept**

Intelligent system suitability check

The AGILENT TECHNOLOGIES ChemStation includes intelligent system suitability testing in which users measure and compare critical key system performance characteristics with documented, preset limits.

For example, users could inject a well characterized standard five or six times and then compare the standard deviation of the amounts with a predefined value. If the limits of detection and quantitation are critical, users should test the lamp's intensity profile or the baseline noise.

Maintenance Checklists, Early Maintenance Feedback and Maintenance Logbooks.

Users of equipment are required to develop an ongoing maintenance and calibration program. The idea of the preventive maintenance is to avoid instrument failures.

If in FDA regulated pharmaceutical quality control laboratories a specific analysis is out of specification, for any reason, it is no longer acceptable to just adjust a few parameters, to repeat the analysis and average the results. For each out of specification analysis, a failure investigation has to be done (4). Therefore laboratories do their utmost to maintain instruments such that false results are avoided.

The AGILENT TECHNOLOGIES 1200 Early Maintenance Feedback (EMF) system informs the user when actual usage level have exceeded their user specified limits. Examples are:

- usage of detector lamps,
- mobile phase usage and wear counts,
- number of injections.

In addition maintenance activities can be performed by trained customer engineers on a timely basis. The maintenance activities should be documented in the electronic logbook.

### **Contribution of the Qualification Workbook**

The chapter Performance Qualification (PQ) phase contains examples of documents to demonstrate that the equipment performs according to a specification for its routine use. It also contains documents to show that it is well maintained. Typical examples are:

- System suitability reports
- Copies of maintenance logbooks
- Maintenance checklists

System suitability reports have to be updated by the user depending on the frequency determined during method development and validation of the method. The other documents need to be updated based on EMF information and whenever Planned/Preventive Maintenance is performed.

Heinz Goetz, Ph.D.  
1200 Series Worldwide Product Manager  
AGILENT TECHNOLOGIES R&D and Marketing GmbH & Co. KG  
Ger-76337 Waldbronn

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- (3) P. Bedson, M. Sargent, Accreditation and Quality Assurance 1 (6), 265-274 (1996)
- (4) United States FDA, Guide to Inspection of Pharmaceutical Quality Control Laboratories, Final Rule, USA FDA, Rockville, 1993

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## Agilent's line of proven qualification products and services

Agilent has been a worldwide Compliance leader for two decades. The unmatched experience of our experts goes into each of our compliance services. Agilent can provide you with the compliance tools, knowledge, service and support necessary to keep your lab operating smoothly and efficiently. For an overview refer to the brochure "

Can you take the heat - Don't get burned by compliance". On the next pages you find the brochure.

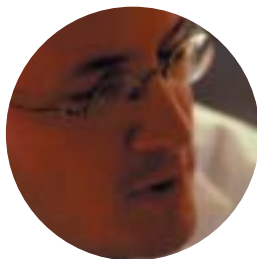
**Can you take the heat**

Don't get burned by compliance



**Agilent Technologies**

## Agilent's line of proven qualification products and services takes the heat off you...and your lab



### **The one-source solution for qualification and validation**

Compliance is a necessary and demanding load on a lab's resources. If not well managed and implemented it can become a growing inferno, which can lead to severe penalties and financial consequences. In addition, compliance standards are constantly evolving and therefore create a "moving target" and a significant source of stress for those involved in the process. Let Agilent remove the stress of compliance and take the heat off you and your lab – once and for all. Then, your lab can focus on analytical results, not extinguishing the flames of non-compliance.

Agilent provides the most complete line of compliance products and services available – allowing labs to select service for Agilent instruments, Agilent software and even products from other manufacturers. Agilent offers a complete compliance program that enables lab managers to make one call for any or all of their needs – no matter what the brand, no matter what the service. Agilent offers customer-focused products and services for all stages of an instrument's life cycle. From installation and upgrade to operation and repair – Agilent provides the resources and tools necessary to ensure compliance is not a burning issue.

### **Overall benefits:**

- Provide evidence to satisfy requirements of monitoring agencies and organizations.
- Save time and money by eliminating the need to write your own operating procedures or monographs and training your staff.
- Ensure that all equipment is performing to manufacturers' standards.
- Receive uniform documentation that provides consistent, traceable results among all locations – worldwide.
- Decrease risk of financial loss due to noncompliance.
- Reduce complexity of scheduling multiple vendors.
- Allow scientists and staff to focus on research, not compliance.

## When compliance heats up, Agilent keeps you cool

### **Compliance products and services for Agilent instruments**

An investment in Agilent instruments ensures maximum productivity. To maintain the highest level of operation, a suite of products and services is available. These products and services take into account the various phases of an instrument's life cycle and allow the lab to customize a compliance program based on specific needs. From installation to ongoing support, Agilent has compliance covered.

### **Installation Qualification (IQ) provides validation upon delivery**

IQ ensures that new Agilent hardware and software is installed correctly from the moment it is unpacked to the point it is ready for operation – documenting the completeness of shipping, the operating environment and the components of the system.

### **Recommended times for IQ**

- Moving an instrument to another laboratory
- Adding components to an instrument
- Installing hardware or software
- Installing a software patch, update or other application

### **Operational Qualification (OQ) ensures basic accuracy from the beginning**

After IQ, OQ is performed to verify and document an Agilent instrument's ability to meet specified performance criteria after it is installed. OQ involves a comprehensive test of the complete system using established conditions and known sample characteristics. A key benefit to this procedure is to ensure the basic accuracy and precision of the instrument or system and to uncover any potential problems before they occur. Agilent recommends preventive maintenance for OQ.

### **Recommended times for OQ**

- Installing hardware or software
- Repairing a major piece of hardware
- Any software change that affect system security, data integrity or administrative controls

### **Repair Qualification (RQ) restores equipment validation**

RQ is a must for any service or maintenance performed on Agilent instruments. RQ provides documented evidence that proper techniques and procedures are utilized. This is accomplished through ISO trained technicians who use traceable, documented tools and equipment to ensure that the work they do meets all facets of compliance.

### **Performance Qualification (PQ) maximizes uptime and productivity**

PQ is a method for a lab to perform ongoing self-validation and is an excellent way to head off potential problems before they occur. Small problems can be identified and remedied, before they become costly. In addition, consistent PQ allows formal compliance procedures to move much more rapidly because there are traceable paths of documentation demonstrating prior inspections and service.

To support a lab's PQ program, Agilent offers preventive maintenance services to ensure maximum instrument uptime and extended life. Agilent's service professionals can perform a documented list of maintenance procedures on your instrument prior to performing a qualification procedure. Preventive maintenance can be scheduled to coincide with PQ to minimize instrument downtime.

A lab's validation plan or change control program should define when it needs to qualify instruments and software to ensure compliance with quality and regulatory requirements.



# Compliance solutions for all Agilent software

Accurate data management is critical to a lab's total compliance agenda. Agilent offers a range of products to help facilitate information handling and security. This variety allows a lab to maintain compliance from the day software is installed, through everyday use, and into upgrade and service – providing continued productivity with minimal downtime.

## Design Qualification (DQ) is a step in the right direction

The first step in any compliance program is Design Qualification. This process requires the lab to document user requirements and Agilent instrument functional/operational specifications. The instrument vendor also has to be qualified for appropriate software development processes. To assist the lab in this process, Agilent utilizes an extensive list of functional specifications for computer systems that allows applicable functions and specifications to be qualified for their intended uses. Agilent also provides documented evidence that software and computer systems have been developed and validated according to standardized procedures such as ISO 9001.

## ChemStation Plus NDS – Modular software for more control and more productivity

The ChemStation family provides a modular approach to instrument control, data acquisition and data management, allowing a lab to choose a system that meets current and future needs. To accommodate these changing needs, the scalable solution starts with ChemStation base software and add-on software modules that cover security and compliance to expand the system's capabilities.

### ChemStation

Start with the ChemStation base software for control of LC, LC/MS, GC, CE and CE/MS instruments, then expand the system's power with add-on modules for data organization and storage remote control and monitoring, compliance with regulator guidelines and for validation of analytical methods.



Level-4 instrument control provides for diagnostics that enable a lab to interpret instrument systems and perform repairs on-site.

### ChemStation Plus

Incorporates the ChemStation base software, plus allows the addition of any of the available add-on modules.

### ChemAccess

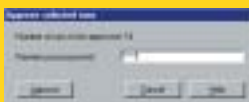
Provides the ability to control and monitor Agilent instruments from anywhere on the network.

### Security Pack

Add Security Pack to accelerate review and approval of results as well as provide support of regulatory requirements such as the FDA's ruling on electronic records and signatures, 21 CFR Part 11.



Built-in user administration allows only authorized users to connect to the database.



Electronic signatures for full support of 21 CFR Part 11.

**Method Validation (MV) qualifies the process to make your work easier**

If the analytical method isn't validated, then qualified instruments don't matter. Method Validation is yet another critical component in the compliance process. Methods must be validated after their development and prior to routine use. And if any parameter is changed significantly, the method must be validated again. Agilent's MV products will ensure that processes meet the standards of such organizations as United States Pharmacopoeia (USP) and the International Conference on Harmonization (ICH). One such product is the Method Validation Pack available for the Agilent ChemStation Plus software package and is just one of many software solutions for all validation needs.

**Cerity Networked Data Systems – Lab-specific software for smoother workflow**

The Cerity NDS family provides lab-specific software applications that model the way analysts work, making every step of the lab's workflow more efficient. For regulated environments, the Cerity NDS for Pharmaceutical QA/QC provides a secure data management system where procedures must be followed according to compliance requirements such as 21 CFR Part 11. Version control, inherent data integrity and security, and an automatic, fully traceable audit trail ensure no records can be overwritten.

**Method Validation Pack**

Add Method Validation Pack to support the validation of analytical methods according to ICH and Pharmacopoeia requirements as well as 21 CFR Part 11.



Validation planning according to USP, EP, ICH and FDA guidelines.



A complete test suite meets the major industry method validation guidelines.

**Cerity NDS for Pharmaceutical QA/QC**

Specifically designed to meet the unique and wide-ranging requirements of QA/QC labs in the pharmaceutical industry.



Level-4 control of networked instruments means reliable, trustworthy and traceable data.



Built-in spreadsheet eliminates manual data transcription, lowering validation costs.



## Agilent can train you and your staff to avoid compliance flare ups

Agilent offers broad-scope training courses for regulatory compliance to ensure research methods are up to date and suitable for specific purposes. In addition, training will enable lab staff to create traceable chains that provide the complete records required by regulatory agencies to demonstrate proper laboratory analyses.

Agilent has a comprehensive training curriculum dedicated to the needs of the pharmaceutical industry. These courses offer basic and advanced training in liquid chromatography techniques, chemical analysis hardware and software operation as well as data analysis and reporting. These courses allow the pharmaceutical laboratory to use chemical analysis instruments at their most productive levels – giving greater return on investment for all lab resources. In addition, courses cover methods to improve the quality of data and how to improve troubleshooting skills.

For convenience, standardized courses are offered in select locations worldwide. Or, on-site courses can be tailored to specific needs and time frames. For the ultimate in convenience, Agilent offers e-seminars as a way to advance knowledge and improve lab skills on a specific subject. Each seminar lasts between 60 and 90 minutes and enables researchers to gather usable information from their desktops – eliminating expensive and time-consuming travel. Agilent e-seminars keep scientists up to date on pertinent qualification techniques and procedures, troubleshooting and system optimization techniques.

Featuring a user-friendly internet conferencing system that allows you to interact with the speaker, e-seminars enable the attendee to participate from the office, home or out of town using a basic internet connection and a browser such as Microsoft® Internet Explorer or Netscape Navigator. You can find a complete listing of compliance related e-seminars at:  
[www.agilent.com/chem/eseminars](http://www.agilent.com/chem/eseminars).

### Training courses for regulatory compliance in the pharmaceutical industry

**Instrumentation Qualification** – This IQ/OQ course covers the basic principles of chromatography instrument operation, focusing on design qualification (DQ), installation qualification (IQ), and operational qualification (OQ) for liquid chromatographs, UV-Vis spectrophotometers, infrared spectrometers and automated workstations.

**Method Validation** – This course covers why an analytical method should be validated and which parameters must be validated for pharmaceutical applications. In addition, this course reviews current techniques of method validation, shows the steps for validating a method, describes how data is obtained, and explains how to ensure that a method is appropriate for the purpose. It uses practical pharmaceutical examples to demonstrate how method validation works within ISO and GMP/GLP environments.



### **Multi-Vendor Validation Program\* offers a single solution**

Compliance offers enough challenges on its own – then consider that many labs utilize many different brands of instruments. The task can be daunting. Agilent offers a solution based on a single set of protocols applicable across a variety of instruments, regardless of manufacturer. Laboratories that are seeking methods to streamline experiments and increase productivity can rely on the Multi-Vendor Validation Program. It allows a lab manager to make one call, schedule one vendor, and keep disruption to an absolute minimum. This program can be applied to many instruments, including the following:

- UV Spectrophotometer
- Liquid Chromatograph (LC)
- LC/MS
- Gas Chromatograph (GC)
- GC/MS
- Dissolution Tester
- Capillary Electrophoresis

*\*Not available in all areas.*

### **Multi-Vendor Validation Program benefits**

- A single master plan that is simplified for ease of use.
- Harmonization of protocols to reduce effort of instrument validation.
- Coverage of all instruments, regardless of manufacturer, from a single vendor.
- Unique, metrology-based technique made possible by the GLP-100, a proprietary test-box tool that measures the basic physical parameters of your instruments.
- A customizable program with qualifications performed under test conditions and parameter ranges you design.

### **International protocol acceptance**

There are a variety of national and international regulatory and quality standards that require laboratory equipment be validated upon installation and after upgrade or repair. Agilent qualification protocols have a proven record of success in satisfying these requirements. Agilent protocols have gone unchallenged in numerous audits worldwide.

Agilent's protocols have been designed to comply with regulations and standards such as:

- GMP of US FDA and other agencies
- GLP of US FDA, OECD and other agencies
- 21 CFR Part 11 on e-records/signatures
- ISO 17025 (replaces EN 45000/45001)
- ISO 9000 series

### **For more information regarding a successful compliance program**

Go to [www.agilent.com/chem](http://www.agilent.com/chem) and look up our online brochure, "5-Step Concept to Successful Compliance." #5988-7026EN

### **Expert advice from the expert himself**

To facilitate international compliance programs, products and services, Agilent employs experts like Ludwig Huber, Ph.D (Worldwide Product Marketing Manager for HPLC products and pharmaceutical industry solutions at Agilent Technologies). Dr. Huber serves as a consultant for industry and regulatory agencies on laboratory compliance issues like the US PDA task force on 21 CFR Part 11 and on the GAMP Special Interest Group for Laboratory Equipment. He is also on the advisory board for the European Compliance Academy.

It is this sort of expertise that drives our compliance programs and enables them to deliver the results your lab demands. This level of experience and wealth of knowledge is available online, by registering for one of the many e-seminars, by contacting the Agilent compliance team directly at [www.agilent.com/chem](http://www.agilent.com/chem) or by contacting Dr. Huber directly at [ludwig\\_huber@agilent.com](mailto:ludwig_huber@agilent.com) or via telephone at +49 7243 602209.

**"It is our goal to allow Agilent customers to comply at the lowest cost and with the highest confidence."**

*– Dr. Ludwig Huber*



For more information visit us at: [www.agilent.com/chem](http://www.agilent.com/chem)

**Confidence is knowing you'll never  
be burned by compliance**

Confidence begins with knowing that Agilent's internal procedures are as exact and traceable as the procedures we employ at laboratories worldwide.

We utilize exact documentation paths to create, test and review the products and services we offer. Our service professionals arrive at your site trained and certified under a factory program registered to ISO 9001 – with training records for our service professionals available upon request. Each service professional carries calibrated and traceable tools, testing equipment and standards for the rigorous tests needed to verify instrument performance. For these reasons, Agilent is recognized as the premier supplier of compliance products and services around the world. It is a reputation that has been earned audit after audit – lab after lab.

Agilent can provide your lab with the tools, knowledge, service and support necessary to keep it operating smoothly and efficiently. It's our mission to keep you on your mission – and to keep you cool when things heat up. Agilent can't eliminate the need for compliance, but our blanket of support can help smother any potential fires.

To obtain detailed information about Agilent's qualification and support services, please call 1-800-227-9770 in the U.S. and Canada. In other regions of the world, please contact your Agilent Technologies sales office and ask for a chemical analysis representative.

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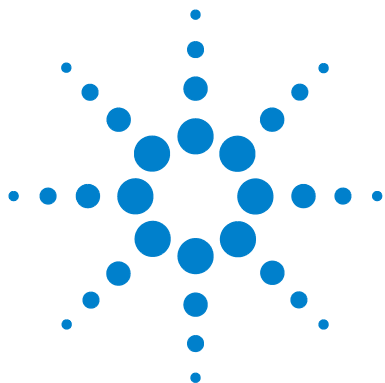
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**Agilent Technologies**

## **1 Overview**

Agilent's line of proven qualification products and services



## 2

## Design Qualification (DQ) Phase

Iso 90001: Valid June 2006 Certificate  
Specifications

Pump Specifications

Injection Systems Specifications

Detectors Specifications

Fraction Collectors Specifications

Valves Specifications

Miscellaneous Specifications

Agilent ChemStation Specifications

Agilent ChemStation Plus Specifications

Compliance

Customer contributed documents

The user should feel free to add further documents, e.g. not supplied by Agilent Technologies whenever he thinks this is appropriate.



## **Iso 90001: Valid June 2006 Certificate**



Affiliate with the N.V. KEMA in the Netherlands

A member of the International Network for Quality System Assessment and Certification "IQNet"

# CERTIFICATE

Certificate Number: 510014.045

With two page addendum

The Quality System of:

**Agilent Technologies, Inc.  
Life Sciences and Chemical Analysis Group  
Americas, Europe and Asia Pacific**

Including its implementation, meets the requirements of the standard:

## ISO 9001:2000

**Scope:**

Design, development, manufacture, marketing, distribution and support of analytical instrumentation, systems and microarray systems including related software, services, chromatography columns, packing, reagents, and consumables.

This Certificate is valid until:	June 1, 2006
This Certificate is valid as of:	February 10, 2006
Certified for the first time:	February 1, 1994

H. Pierre Sallé

President

KEMA-Registered Quality

The method of operation for quality certification is defined in the KEMA General Terms And Conditions For Quality And Environmental Management Systems Certifications. Integral publication of this certificate is allowed.

**KEMA-Registered Quality, Inc.**

4377 County Line Road

Chalfont, PA 18914

Ph: (215)997-4519

Fax: (215)997-3809

CRT 001 073004

**Accredited By:**

ANAB



# ADDENDUM

To Certificate Number: 510014.045 (ISO 9001:2000) of February 1, 1994  
Valid as of: October 27, 2005  
Valid until: June 1, 2006  
Page one of two

The Quality System of:

## **Agilent Technologies, Inc. Life Sciences and Chemical Analysis Group**

Waldbronn Analytical Division Hewlett-Packard-Strasse 8 Waldbronn, Germany 76337  
Yokogawa Analytical Systems Inc. 9-1 Takakura-Cho, Hachioji-Shi Tokyo, Japan  
(initial certification date December 28, 1994)

Agilent Technologies Shanghai No. 412 Ying Lun Road Shanghai, PRC

Little Falls Site 2850 Centerville Road Wilmington, Delaware

Newport Site 101 First State Blvd. Newport, Delaware

Folsom Site 91 Blue Ravine Road Folsom, CA

Santa Clara Site 5301 Stevens Creek Blvd. Santa Clara, CA

Chemical Analysis Logistics Center - Americas Twin Spans Industrial Park, 500 Ships  
Landing Way New Castle, DE 19720

Pleasanton Site - 6612 Owens Drive, Pleasanton, CA



H. Pierre Sallé  
President  
KEMA-Registered Quality

The method of operation for quality certification is defined in the KEMA General Terms  
And Conditions For Quality And Environmental Management Systems Certifications.  
Integral publication of this certificate is allowed.



Affiliate with the N.V. KEMA in the Netherlands  
A member of the International Network for Quality System Assessment and Certification "IQNet"

# ADDENDUM

To Certificate Number: 510014.045 (ISO 9001:2000) of February 1, 1994  
Valid as of: February 10, 2006  
Valid until: June 1, 2006  
Page two of two

The Quality System of:

## **Agilent Technologies, Inc. Life Sciences and Chemical Analysis Group**

Customer Support activities including Compliance Services, Installation, Repair and Onsite maintenance of analytical test equipment in Chromatography, Spectrometry, Laboratory Automation and Laboratory Information Technology equipment, project consultancy and user training in the Austria, Belgium, Brazil, Canada, Denmark, Finland, France, Germany, Ireland, Italy, Luxemburg, the Netherlands, Sweden, Spain, Switzerland, the United Kingdom, and the United States.

Customer Sales and Support activities including Sale of equipment, Compliance Services, Installation, Repair and Onsite maintenance of analytical test equipment in Chromatography, Spectrometry, Laboratory Automation and Laboratory Information Technology equipment, project consultancy and user Training in Australia.

Centralized Support from the following: Analytical Response Center - Europe (Amstelveen) – United States (Little Falls, DE); Central Call management, Customer Engineer training and the provision of Software Support (internal and to customers)

Field Support Centers located in Germany (EFSC - Waldbronn) and the United States (AFSC – Little Falls, DE); Brazil and Mexico, Call management, CE-Assist for Hardware, products, escalation management, Customer Engineer training

Field Repair Centers located in Germany (ERC - Waldbronn) and the United States (ERC Little Falls, DE); and Mexico, Centralized Bench Repair Services and Instrument Exchange program

Business Centers located in Spain (Barcelona) and the United States (Little Falls, DE); Order fulfillment of standard and supplied products and services concerning analytical test equipment in Chromatography, Spectrometry, Laboratory Automation and Laboratory Information technology equipment.

H. Pierre Sallé  
President  
KEMA-Registered Quality

The method of operation for quality certification is defined in the KEMA General Terms And Conditions For Quality And Environmental Management Systems Certifications.  
Integral publication of this certificate is allowed.

**KEMA-Registered Quality, Inc.**  
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Chalfont, PA 18914  
Ph: (215)997-4519  
Fax: (215)997-3809

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ANAB



# Pump Specifications

## G1310A Isocratic Pump

### Performance Specifications

**Table 1** Performance Specification Agilent 1200 Isocratic Pump

Type	Specification
Hydraulic system	Dual piston in series pump with proprietary servo-controlled variable stroke drive, floating pistons and active inlet valve
Setable flow range	0.001 – 10 ml/min, in 0.001 ml/min increments
Flow range	0.2 – 10.0 ml/min
Flow precision	≤0.07% RSD, or ≤0.02 min SD whatever is greater, based on retention time at constant room temperature
Flow accuracy	±1% or 10µl/min whatever is greater
Pressure	Operating range 0 – 40 MPa (0 – 400 bar, 0 – 5880 psi) up to 5 ml/min Operating range 0 – 20 MPa (0 – 200 bar, 0 – 2950 psi) up to 10 ml/min
Pressure pulsation	< 2 %amplitude (typically < 1 %), at 1 ml/min isopropanol, at all pressures > 10 bar (147 psi)
Compressibility compensation	User-selectable, based on mobile phase compressibility
Recommended pH range	1.0 – 12.5, solvents with pH < 2.3 should not contain acids which attack stainless steel
Control and data evaluation	Agilent ChemStation for LC
Analog output	For pressure monitoring, 2 mV/bar, one output
Communications	Controller-area network (CAN), GPIB, RS-232C, APG Remote: ready, start, stop and shut-down signals, LAN optional

## 2 Design Qualification (DQ) Phase

### Pump Specifications

**Table 1** Performance Specification Agilent 1200 Isocratic Pump(continued)

Safety and maintenance	Extensive diagnostics, error detection and display (through control module and Agilent ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.
GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of seal wear and volume of pumped mobile phase with user-settable limits and feedback messages. Electronic records of maintenance and errors.
Housing	All materials recyclable.

#### NOTE

For use with flow rates below 500 µl/min a vacuum degasser is required.

### Physical Specifications

**Table 2** Physical Specifications

Type	Specification	Comments
Weight	11 kg (25 lbs)	
Dimensions (height × weight × depth)	140 × 345 × 435 mm (5.5 × 13.5 × 17 inches)	
Line voltage	100 – 120 or 220 – 240 VAC, ± 10 %	Wide-ranging capability
Line frequency	50 or 60 Hz, ± 5 %	
Power consumption	220 VA	Maximum
Ambient operating temperature	4 – 55 °C (41 – 131 °F)	
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	

**Table 2**    Physical Specifications(continued)

Non-operating altitude	Up to 4600 m (14950 ft)	For storing the isocratic pump
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2	

## G1311A Quaternary Pump

### Performance Specifications

**Table 3** Performance Specification Agilent 1200 Quaternary Pump

Type	Specification
Hydraulic system	Dual plunger in series pump with proprietary servo-controlled variable stroke drive, floating plungers and active inlet valve
Setable flow range	0.001 – 10 ml/min, in 0.001 ml/min increments
Flow range	0.2 – 10.0 ml/min
Flow precision	≤0.07% RSD, or ≤0.02 min SD whatever is greater, based on retention time at constant room temperature
Flow accuracy	±1% or 10µl/min whatever is greater
Pressure	Operating range 0 – 40 MPa (0 – 400 bar, 0 – 5880 psi) up to 5 ml/min Operating range 0 – 20 MPa (0 – 200 bar, 0 – 2950 psi) up to 10 ml/min
Pressure pulsation	< 2 %amplitude (typically < 1 %), at 1 ml/min isopropanol, at all pressures > 1 MPa (10bar)
Compressibility compensation	User-selectable, based on mobile phase compressibility
Recommended pH range	1.0 – 12.5, solvents with pH < 2.3 should not contain acids which attack stainless steel
Gradient formation	Low pressure quaternary mixing/gradient capability using proprietary high-speed proportioning valve Delay volume 800 – 1100 µl, dependent on back pressure
Composition Range	0 – 95 % or 5 – 100 %, user selectable
Composition Precision	< 0.2 % RSD, at 0.2 and 1 ml/min
Control and data evaluation	Agilent ChemStation for LC
Analog output	For pressure monitoring, 2 mV/bar, one output
Communications	Controller-area network (CAN), GPIB, RS-232C, APG Remote: ready, start, stop and shut-down signals, LAN optional

**Table 3** Performance Specification Agilent 1200 Quaternary Pump(continued)

Safety and maintenance	Extensive diagnostics, error detection and display (through control module and Agilent ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.
GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of seal wear and volume of pumped mobile phase with user-settable limits and feedback messages. Electronic records of maintenance and errors.
Housing	All materials recyclable.

## Physical Specifications

**Table 4** Physical Specifications

Type	Specification	Comments
Weight	11 kg (25 lbs)	
Dimensions (height × weight × depth)	140 × 345 × 435 mm (5.5 × 13.5 × 17 inches)	
Line voltage	100–120 or 220–240 VAC, ± 10%	Wide-ranging capability
Line frequency	50 or 60 Hz, ± 5%	
Power consumption	220 VA	Maximum
Ambient operating temperature	4–55 °C (41–131 °F)	
Ambient non-operating temperature	-40–70 °C (-4–158 °F)	
Humidity	< 95%, at 25–40 °C (77–104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the quaternary pump
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2	

## G1312A Binary Pump

### Performance Specifications

**Table 5** Performance Specification Agilent 1200 Binary Pump

Type	Specification
Hydraulic system	Two dual piston in series pumps with proprietary servo-controlled variable stroke drive, floating piston design and active inlet valve
Setable flow range	Setpoints 0.001 – 5 ml/min, in 0.001 ml/min increments
Flow range	0.1 – 5.0 ml/min
Flow precision	≤0.07% RSD, or ≤0.02 min SD whatever is greater, based on retention time at constant room temperature
Flow accuracy	±1% or 10 µl/min whatever is greater
Pressure	Operating range 0 400 bar (0 – 5880 psi) up to 5 ml/min
Pressure pulsation	< 2 % amplitude (typically < 1 %), at 1 ml/min isopropanol, at all pressures > 1 MPa
Compressibility compensation	User-selectable, based on mobile phase compressibility
Recommended pH range	1.0 – 12.5, solvents with pH < 2.3 should not contain acids which attack stainless steel
Gradient formation	High-pressure binary mixing, delay volume 180 – 480 µl without mixer, 600 – 900 µl with mixer, dependent on back pressure
Composition range	1 – 99 % or 5 µl/min per channel, whatever is greater
Composition precision	±0.5% absolute
Composition accuracy	±0.15% RSD, at 1 ml/min
Control and data evaluation	Agilent ChemStation for LC
Analog output	For pressure monitoring, 2 mV/bar, one output
Communications	Controller-area network (CAN), GPIB, RS-232C, APG Remote: ready, start, stop and shut-down signals, LAN optional

**Table 5** Performance Specification Agilent 1200 Binary Pump(continued)

Safety and maintenance	Extensive diagnostics, error detection and display (through handheld controllers G4208A, G1323B and Agilent ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.
GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of seal wear and volume of pumped mobile phase with user-settable limits and feedback messages. Electronic records of maintenance and errors.
Housing	All materials recyclable.

**NOTE**

For use with flow rates below 500 µl/min a vacuum degasser is required.

## Physical Specifications

**Table 6** Physical Specifications

Type	Specification	Comments
Weight	15.5 kg (34 lbs)	
Dimensions (height × weight × depth)	180 × 345 × 435 mm (7 × 13.5 × 17 inches)	
Line voltage	100 – 120 or 220 – 240 VAC, ± 10 %	Wide-ranging capability
Line frequency	50 or 60 Hz, ± 5 %	
Power consumption	220 VA	Maximum
Ambient operating temperature	4 – 55 °C (41 – 131 °F)	
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	

**2    Design Qualification (DQ) Phase**  
**Pump Specifications**

**Table 6**    Physical Specifications(continued)

Non-operating altitude	Up to 4600 m (14950 ft)	For storing the binary pump
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2	

## G1312B Binary Pump SL

### Performance Specifications

**Table 7** Performance Specifications of the Agilent 1200 Series Binary Pump SL

Type	Specification	Comments
Hydraulic system	Two dual piston in series pumps with proprietary servo-controlled variable stroke drive, floating piston design and active inlet valve	
Setable flow range	Setpoints 0.001 – 5 mL/min, in 0.001 mL/min increments	
Flow range	0.05 – 5.0 mL/min	
Flow precision	$\leq 0.07\%$ RSD or $\leq 0.02$ min SD, whatever is greater	based on retention time at constant room temperature
Flow accuracy	$\pm 1\%$ or 10 $\mu\text{L/min}$ , what ever is greater	measured with water
Pressure	Operating range 0 – 600 bar (0 – 7800 psi) up to 5 ml/min	
Pressure pulsation	<b>Standard delay volume configuration:</b> < 2% amplitude (typically < 1%) <b>Low delay volume configuration:</b> < 5% amplitude (typically < 2%)	at 1 mL/min water, at all pressures > 1 MPa
Compressibility compensation	Automatic, pre-defined, based on mobile phase compressibility	
Recommended pH range	1.0 – 12.5	Solvents with pH < 2.3 should not contain acids which attack stainless steel.
Gradient formation	High-pressure binary mixing	

## 2 Design Qualification (DQ) Phase

### Pump Specifications

**Table 7** Performance Specifications of the Agilent 1200 Series Binary Pump SL(continued)

Type	Specification	Comments
Delay volume	<b>Standard delay volume configuration:</b> 600-800 µl, dependent on back pressure (includes 400 µl mixer) <b>Low delay volume configuration:</b> 120 µl	measured with water
Composition range	settable range: 0 – 100% recommended range: 1 – 99 % or 5 µl/min per channel, whatever is greater	
Composition precision	< 0.15 % RSD	at 1mL/min
Composition accuracy	± 0.35% absolute	(water/caffeine tracer)
Control	Agilent ChemStation for LC (32-bit) G4208A Handheld Controller EZ Chrom Elite	Revision B.02.00 or above
Analog output	For pressure monitoring, 1.33 mV/bar, one output	
Communications	Controller-area network (CAN), RS-232C, APG Remote: ready, start, stop and shut-down signals, LAN optional	
Safety and maintenance	Extensive diagnostics, error detection and display (through Agilent LC Diagnostics), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.	

**Table 7** Performance Specifications of the Agilent 1200 Series Binary Pump SL(continued)

Type	Specification	Comments
GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of seal wear and volume of pumped mobile phase with pre-defined and user-settable limits and feedback messages. Electronic records of maintenance and errors.	
Housing	All materials recyclable.	

**NOTE**

For use with flow rates below 500 µl/min or for use without damper and mixer a vacuum degasser is required.

All specification measurements are done with degassed solvents.

**Physical Specifications****Table 8** Physical Specifications

Type	Specification	Comments
Weight	15.5 kg (34 lbs)	
Dimensions (width × depth × height)	180 × 345 × 435 mm (7 × 13.5 × 17 inches)	
Line voltage	100 – 240 VAC, ± 10 %	Wide-ranging capability
Line frequency	50 or 60 Hz ± 5 %	
Power consumption (G1312B)	160 VA	Maximum
Ambient operating temperature	0 – 55 °C (32 – 131 °F)	.
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	

**Table 8** Physical Specifications(continued)

Humidity	< 95%, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	storage conditions
Safety standards: IEC, CSA, UL, EN	Installation category II, pollution degree 2	

## G1361A Preparative Pump

### Performance Specifications

**Table 9** Performance Specification Agilent 1200 Series Preparative Pump

Type	Specification
Hydraulic system	Dual pistons in parallel
Settable flow range	0.001 – 100 ml/min
Flow precision	< 0.5 % RSD
Pressure range	20 to 400 bar (5880 psi) system pressure
Compressibility compensation	User-selectable, based on mobile phase compressibility
Recommended pH range	1.0 – 12.5, solvents with pH < 2.3 should not contain acids which attack stainless steel.
Control and data evaluation	Agilent ChemStation for LC
Communications	Controller-area network (CAN), RS-232, APG Remote: ready, start, stop and shut-down signals, CAN-DC OUT, LAN optional
Safety and maintenance	Extensive diagnostics, error detection and display (through control module and Agilent ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.

**Table 9** Performance Specification Agilent 1200 Series Preparative Pump(continued)

GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of seal wear and volume of pumped mobile phase with user-settable limits and feedback messages. Electronic records of maintenance and errors.
Housing	All materials recyclable.

Physical Specifications

**Table 10** Physical Specifications - Preparative Pump

Type	Specification	Comments
Weight	15.0 kg	
Dimensions (height × width × depth)	200 × 345 × 440 mm (8 × 13.5 × 18 inches)	
Line voltage	100 – 240 VAC, ± 10 %	Wide-ranging capability
Line frequency	50 – 60 Hz, ± 5 %	
Power consumption	250 VA	Maximum
Ambient operating temperature	4 – 40 °C (41 – 104 °F)	
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the preparative pump
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2	for indoor use only!

## G1376A Capillary Pump

### Performance Specifications

**Table 11** Performance Specification Agilent 1200 Series Capillary Pump

Type	Specification
Hydraulic system	Two dual piston in series, with proprietary servo-controlled variable stroke drive, floating piston, active inlet valve, solvent selection valve and electronic flow control for flow rates up to 100 µl/min
Settable column flow range	0.01 – 20 µl/min 0.01 – 100 µl/min (with the extended flow range kit) 0.001 – 2.5 µl/min (with the electronic flow control bypassed)
Recommended column flow range	1 – 20 µl/min 10 – 100 µl/min (with extended flow range kit) 0.1 – 2.5 ml/min (with the electronic flow sensor bypassed)
Column flow precision	< 0.7 % RSD or 0.03 % SD (typically 0.4 % RSD or 0.02 % SD), at 10 µl/min and 50 µl/min column flow (based on RT, default setting)
Optimum composition range	1 to 99% or 5 µl/min per channel (primary flow), whatever is greater
Composition precision	< 0.2 % SD, at 10 µl/min (20 µl flow sensor), 50 µl/min (100 µl flow sensor) and 1 ml/min (normal mode) default setting
Delay volume	Typically 3 µl from the electronic flow control to the pump outlet for flow rates up to 20 µl/min. Typically 12 µl from the electronic flow control to the pump outlet for flow rates up to 100 µl. for flow rates up to 100 µl/min and electronic flow control active: primary flow path 180 - 480 µl without mixer, 600 - 900 µl with mixer (system pressure dependant) Typically 180 to 480 µl (system pressure dependent) without mixer for flow rates up to 2.5 ml/min. (Mixer delay volume 420 µl)
Pressure range	20 to 400 bar (5880 psi) system pressure
Compressibility compensation	User-selectable, based on mobile phase compressibility
Recommended pH range	1.0 – 8.5, solvents with pH < 2.3 should not contain acids which attack stainless steel. Upper pH range is limited by fused silica capillaries.

**Table 11** Performance Specification Agilent 1200 Series Capillary Pump(continued)

Control and data evaluation	Agilent ChemStation for LC
Analog output	For pressure monitoring, 2 mV/bar, one output
Communications	Controller-area network (CAN), GPIB, RS-232C, APG Remote: ready, start, stop and shut-down signals, LAN optional
Safety and maintenance	Extensive diagnostics, error detection and display (through instant pilot and Agilent ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.
GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of seal wear and volume of pumped mobile phase with user-settable limits and feedback messages. Electronic records of maintenance and errors.
Housing	All materials recyclable.

## Physical Specifications

**Table 12** Physical Specifications

Type	Specification	Comments
Weight	17 kg (39 lbs)	
Dimensions (height × weight × depth)	180 × 345 × 435 mm (7 × 13.5 × 17 inches)	
Line voltage	100 – 120 or 220 – 240 VAC, ± 10 %	Wide-ranging capability
Line frequency	50 or 60 Hz, ± 5 %	
Power consumption	220 VA	Maximum
Ambient operating temperature	4 to 55 °C (41 to 131 °F)	
Ambient non-operating temperature	-40 to 70 °C (-4 to 158 °F)	

**2    Design Qualification (DQ) Phase**  
**Pump Specifications**

**Table 12**    Physical Specifications(continued)

Humidity	< 95 %, at 25 to 40 °C (77 to 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the autosampler
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2	

## G2226A Nano Pump

### Performance Specifications

**Table 13** Performance Specification Agilent 1200 Series Nano Pump

Type	Specification
Hydraulic system	Two dual piston in series, with proprietary servo-controlled variable stroke drive, floating piston, active inlet valve, solvent selection valve and electronic flow control for flow rates from 0.1 to 1 µl/min
Settable column flow range	0.01 – 4 µl/min 1 – 2500 µl/min (with the electronic flow control bypassed)
Recommended column flow range	0.1 – 1 µl/min 200 – 2500 µl/min (with the electronic flow sensor bypassed)
Optimum composition range	1 to 99% or 5 µl/min per channel (primary flow), whatever is greater
Composition precision	< 0.2 % SD, at 500 nl/min (default settings), Minimum primary flow/pump channel is 5 µl/min
Delay volume	Typically 300 nl from the electronic flow control to the pump outlet for flow rates up to 4 µl/min. For flow rates up to 4 µl/min and electronic flow control active: primary flow path 180 - 480 µl; system pressure dependent (default settings; calculated volume) Typically 180 to 480 µl (system pressure dependent) for flow rates up to 2.5 ml/min. (default settings; calculated volume)
Pressure range	20 to 400 bar (5880 psi) system pressure
Compressibility compensation	User-selectable, based on mobile phase compressibility
Recommended pH range	1.0 – 8.5, solvents with pH < 2.3 should not contain acids which attack stainless steel. Upper pH range is limited by fused silica capillaries.
Control and data evaluation	Agilent ChemStation for LC
Analog output	For pressure monitoring, 2 mV/bar, one output
Communications	Controller-area network (CAN), GPIB, RS-232C, APG Remote: ready, start, stop and shut-down signals, LAN optional

**Table 13** Performance Specification Agilent 1200 Series Nano Pump(continued)

Safety and maintenance	Extensive diagnostics, error detection and display (through control module and Agilent ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.
GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of seal wear and volume of pumped mobile phase with user-settable limits and feedback messages. Electronic records of maintenance and errors.
Housing	All materials recyclable.

## Physical Specifications

**Table 14** Physical Specifications

Type	Specification	Comments
Weight	17 kg (39 lbs)	
Dimensions (height × weight × depth)	180 × 345 × 435 mm (7 × 13.5 × 17 inches)	
Line voltage	100 – 120 or 220 – 240 VAC, ± 10 %	Wide-ranging capability
Line frequency	50 or 60 Hz, ± 5 %	
Power consumption (apparent power) Power consumption (active power)	220 VA 75 W	Maximum Maximum
Ambient operating temperature	4 – 55 °C (41 – 131 °F)	
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the binary pump
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2	

# Injection Systems Specifications

## G1329A Autosampler 100 µl metering head

### Performance Specifications

**Table 15** Performance Specifications Agilent 1200 Autosampler (G1329A). Valid when standard 100 µl metering head installed.

Type	Specification
GLP features	Early maintenance feedback (EMF), electronic records of maintenance and errors
Communications	Controller-area network (CAN). GPIB (IEEE-448), RS232C, APG-remote standard, optional four external contact closures and BCD vial number output
Safety features	Leak detection and safe leak handling, low voltages in maintenance areas, error detection and display
Injection range	0.1 – 100 µl in 0.1 µl increments Up to 1500 µl with multiple draw (hardware modification required)
Replicate injections	1 – 99 from one vial
Precision	< 0.25 % RSD from 5 – 100 µl, < 1 % RSD 1 – 5 µl variable volume
Minimum sample volume	1 µl from 5 µl sample in 100 µl microvial, or 1 µl from 10 µl sample in 300 µl microvial
Carryover	Typically < 0.1 %, < 0.05 % with external needle cleaning
Sample viscosity range	0.2 – 50 cp
Replicate injections per vial	1 – 99
Sample capacity	100 × 2-ml vials in 1 tray 40 × 2-ml vials in ½ tray 15 × 6-ml vials in ½ tray (Agilent vials only)
Injection cycle time	Typically 50 s depending on draw speed and injection volume

## Physical Specifications

**Table 16** Physical Specifications - Autosampler (G1329A / G2260A)

Type	Specification	Comments
Weight	14.2 kg (31.3 lbs)	
Dimensions (height × width × depth)	200 × 345 × 435 mm (8 × 13.5 × 17 inches)	
Line voltage	100 – 120 or 220 – 240 VAC, $\pm 10\%$	Wide-ranging capability
Line frequency	50 or 60 Hz, $\pm 5\%$	
Power consumption (apparent power) Power consumption (active power)	300 VA 200 W	Maximum Maximum
Ambient operating temperature	4 – 55 °C (41 – 131 °F)	see <i>User Manual</i>
Ambient non-operating temperature	-40 to 70 °C (-4 to 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the autosampler
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2 For indoor use only	

## G1329A Autosampler 900 µl metering head

### Performance Specifications

**Table 17** Performance Specifications Agilent 1200 standard autosampler (G1329A).  
Valid when standard 900 µl metering head installed.

Type	Specification
Pressure	Operating range 0-20 MPa (0-200 bar, 0-2950 psi)
GLP features	Early maintenance feedback (EMF), electronic records of maintenance and errors
Communications	Controller-area network (CAN). GPIB (IEEE-448), RS232C, APG-remote standard, optional four external contact closures and BCD vial number output
Safety features	Leak detection and safe leak handling, low voltages in maintenance areas, error detection and display
Injection range	0.1 – 900 µl in 0.1 µl increments (recommended 1 µl increments) Up to 1800 µl with multiple draw (hardware modification required)
Replicate injections	1 – 99 from one vial
Precision	Typically < 0.5 % RSD of peak areas from 5 – 2000 µl, Typically < 1 % RSD of peak areas from 2000 – 5000 µl, Typically < 3 % RSD of peak areas from 1 – 5 µl
Minimum sample volume	1 µl from 5 µl sample in 100 µl microvial, or 1 µl from 10 µl sample in 300 µl microvial
Carryover	Typically < 0.1 %, < 0.05 % with external needle cleaning
Sample viscosity range	0.2 – 50 cp
Sample capacity	100 × 2-ml vials in 1 tray 40 × 2-ml vials in ½ tray 15 × 6-ml vials in ½ tray (Agilent vials only)
Injection cycle time	Typically 50 s, depending on draw speed and injection volume

## Physical Specifications

**Table 18** Physical Specifications - Autosampler (G1329A / G2260A)

Type	Specification	Comments
Weight	14.2 kg (31.3 lbs)	
Dimensions (height × width × depth)	200 × 345 × 435 mm (8 × 13.5 × 17 inches)	
Line voltage	100 – 120 or 220 – 240 VAC, $\pm 10\%$	Wide-ranging capability
Line frequency	50 or 60 Hz, $\pm 5\%$	
Power consumption (apparent power) Power consumption (active power)	300 VA 200 W	Maximum Maximum
Ambient operating temperature	4 – 55 °C (41 – 131 °F)	see <i>User Manual</i>
Ambient non-operating temperature	-40 to 70 °C (-4 to 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the autosampler
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2 For indoor use only	

## G2260A Preparative Autosampler

### Performance Specifications

**Table 19** Performance Specifications Agilent 1200 Preparative Autosampler (G2260A)

Type	Specification
Pressure	Operating range 0-40 MPa (0-400 bar, 0-5800psi)
GLP features	Early maintenance feedback (EMF), electronic records of maintenance and errors
Communications	Controller-area network (CAN). GPIB (IEEE-448), RS232C, APG-remote standard, optional four external contact closures and BCD vial number output
Safety features	Leak detection and safe leak handling, low voltages in maintenance areas, error detection and display
Injection range	0.1 – 900 µl in 0.1 µl increments (recommended 1 µl increments) Up to 1800 µl with multiple draw (hardware modification required) Up to 5000 µl with multiple draw (hardware modification required)
Replicate injections	1 – 99 from one vial
Precision	Typically < 0.5 % RSD of peak areas from 5 – 2000 µl, Typically < 1 % RSD of peak areas from 2000 – 5000 µl, Typically < 3 % RSD of peak areas from 1 – 5 µl
Minimum sample volume	1 µl from 5 µl sample in 100 µl microvial, or 1 µl from 10 µl sample in 300 µl microvial
Carryover	Typically < 0.1 %, < 0.05 % with external needle cleaning
Sample viscosity range	0.2 – 50 cp
Sample capacity	100 × 2-ml vials in 1 tray 15 × 6-ml vials in ½ tray (Agilent vials only)
Injection cycle time	Typically 50 s, depending on draw speed and injection volume

## G1367B High Performance Autosampler and G1367C High Performance Autosampler SL

### Performance Specifications

**Table 20** Performance specifications Agilent 1200 Series High Performance Autosampler and Agilent 1200 Series High Performance Autosampler SL

Type	Specification
GLP features	Early maintenance feedback (EMF), electronic records of maintenance and errors
Communications	Controller-area network (CAN), RS232C, APG-remote standard, optional four external contact closures and BCD vial number output
Safety features	Leak detection and safe leak handling, low voltages in maintenance areas, error detection and display
Injection range	0.1 – 100 µl in 0.1 µl increments Up to 1500 µl with multiple draw (hardware modification required)
Precision	Typically < 0.25 % RSD from 5 – 100 µl, Typically < 1 % RSD from 1 – 5 µl variable volume
Pressure range	G1367B: up to 400 bar (5880 psi) G1367C: up to 600 bar (8700 psi)
Sample viscosity range	0.2 – 5 cp
Sample capacity	2 × well plates (MTP) + 10 × 2 ml vials 108 x 2-mL vials in 2 x 54 vial plate plus 10 additional 2 mL vials 30 x 6-mL vials in 2 x 15 vial plate plus 10 additional 2 mL vials 54 Eppendorf tubes (0.5/1.5/2.0mL) in 2 x 27 Eppendorf tube plate  Also compatible with the Agilent 1200 Series sample capacity extension for further expansion of the sample capacity

**Table 20** Performance specifications Agilent 1200 Series High Performance Autosampler and Agilent 1200 Series High Performance Autosampler SL(continued)

Injection cycle time	Typically < 30 s using following standard conditions: Default draw speed: 200 µl/min Default eject speed: 200 µl/min Injection volume: 5 µl
Carry-over	Typically < 0.01 % using the following conditions: Column: 125 x 4 mm Hypersil ODS, 5 µm Mobile phase: Water/Acetonitrile = 80/20 Flow rate: 1 ml/min Injection volume: 1 µl caffeine (1 mg/ml), 5 µl water to test carryover Outside wash of needle before injection: 20 sec with water using flush port

## Physical Specifications

**Table 21** Physical Specifications - sampler (G1367B/C / G1377A)

Type	Specification	Comments
Weight	15.5 kg (34.2 lbs)	
Dimensions (height × width × depth)	200 × 345 × 440 mm (8 × 13.5 × 17 inches)	
Line voltage	100 – 240 VAC, ±10 %	Wide-ranging capability
Line frequency	50 or 60 Hz, ±5 %	
Power consumption (apparent power)	300 VA	Maximum
Power consumption (active power)	200 W	Maximum
Ambient operating temperature	4 to 55 °C (41 to 131 °F)	
Ambient non-operating temperature	-40 to 70 °C (-4 to 158 °F)	
Humidity	< 95 %, at 25 to 40 °C (77 to 104 °F)	Non-condensing

**2    Design Qualification (DQ) Phase**  
**Injection Systems Specifications**

**Table 21**    Physical Specifications - sampler (G1367B/C / G1377A)(continued)

Type	Specification	Comments
Operating Altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the autosampler
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2	

## G1377A Micro Well plate Sampler

### Performance Specifications

**Table 22** Performance Specifications Agilent 1200 Series Micro Well plate sampler

Type	Specification
GLP features	Early maintenance feedback (EMF), electronic records of maintenance and errors
Communications	Controller-area network (CAN). RS232C, APG-remote standard, optional four external contact closures and BCD vial number output
Safety features	Leak detection and safe leak handling, low voltages in maintenance areas, error detection and display
Injection range	0.01– 8 µl in 0.01 µl increments with the small loop capillary 0.01– 40 µl in 0.01 µl increments with the extended loop capillary
Precision	Typically < 0.5 % RSD of peak areas from 5 – 40 µl, Typically < 1 % RSD from 1 – 5 µl Typically < 3 % RSD from 0.2 – 1 µl
Pressure range	up to 400 bar (5880 psi)
Sample viscosity range	0.2 – 5 cp
Sample capacity	2 × well-plates (MTP) + 10 × 2 mL vials 108 × 2-mL vials in 2 × 54 vial plate plus 10 additional 2 mL vials 30 × 6-mL vials in 2 × 15 vial plate plus 10 additional 2 mL vials 54 Eppendorf tubes (0.5/1.5/2.0mL) in 2 × 27 Eppendorf tube plate
Injection cycle time	Typically < 30 s using following standard conditions: Default draw speed: 4 µl/min Default eject speed: 10 µl/min Injection volume: 0.1 µl
Carry-over	Typically < 0.05 % using the following conditions: Column: 150 × 0.5 mm Hypersil ODS, 3 µm Mobile phase: Water/Acetonitrile = 85/15 Column Flow rate: 13 µl/min Injection volume: 1 µl caffeine (=25ng caffeine), 1 µl water to test carryover Outside wash of needle before injection: 20 sec with water using flush port

# Detectors Specifications

## G1314B Variable Wavelength Detector and G1314C Variable Wavelength Detector SL

### Performance Specifications

**Table 23** Performance Specifications Agilent 1200 Series Variable Wavelength Detector

Type	Specification	Comments
Detection type	Double-beam photometer	
Light source	Deuterium lamp	
Wavelength range	190–600 nm	
Short term noise (ASTM)	$\pm 0.75 \times 10^{-5}$ AU at 254 nm	See NOTE on <a href="#">page 31</a> .
Drift	$3 \times 10^{-4}$ AU/hr at 254 nm	See NOTE on <a href="#">page 31</a>
Linearity	> 2 AU (5%) upper limit	See NOTE on <a href="#">page 31</a>
Wavelength accuracy	$\pm 1$ nm	Self-calibration with deuterium lines, verification with holmium oxide filter
Band width	6.5 nm typical	

**Table 23** Performance Specifications Agilent 1200 Series Variable Wavelength Detector (continued)

Type	Specification	Comments
Flow cells	Standard: 14- $\mu$ l volume, 10-mm cell path length and 40 bar (588 psi) pressure maximum High pressure: 14- $\mu$ l volume, 10-mm cell path length and 400 bar (5880 psi) pressure maximum Micro: 1- $\mu$ l volume, 5-mm cell path length and 40 bar (588 psi) pressure maximum Semi-micro: 5- $\mu$ l volume, 6-mm cell path length and 40 bar (588 psi) pressure maximum	Can be repaired on component level
Control and data evaluation	Agilent ChemStation for LC	
Analog outputs	Recorder/integrator: 100 mV or 1 V, output range 0.001 – 2 AU, one output	
Communications	Controller-area network (CAN), GPIB, RS-232C, APG Remote: ready, start, stop and shut-down signals, LAN optional	GPIB for G1314B only
Safety and maintenance	Extensive diagnostics, error detection and display (through control module and Agilent ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.	
GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of lamp burn time with user-settable limits and feedback messages. Electronic records of maintenance and errors. Verification of wavelength accuracy with built-in holmium oxide filter.	
Housing	All materials recyclable.	

**NOTE**

ASTM: “Standard Practice for Variable Wavelength Photometric Detectors Used in Liquid Chromatography”.

Reference conditions: cell path length 10 mm, response time 2 s, flow 1 ml/min LC-grade methanol.

Linearity measured with caffeine at 265 nm.

## Physical Specifications

**Table 24** Physical Specifications

Type	Specification	Comments
Weight	11 kg 25 lbs	
Dimensions (height × width × depth)	140 × 345 × 435 mm 5.5 × 13.5 × 17 inches	
Line voltage	100 – 240 VAC, $\pm$ 10%	Wide-ranging capability
Line frequency	50 or 60 Hz, $\pm$ 5%	
Power consumption	220 VA, 85 W / 290 BTU	Maximum
Ambient operating temperature	0–55 °C (32–131 °F)	
Ambient non-operating temperature	-40–70 °C (-4–158 °F)	
Humidity	< 95%, at 25–40 °C (77–104 °F)	Non-condensing
Operating altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the instrument
Safety standards: IEC, CSA, UL, EN	Installation Category II, Pollution Degree 2. For indoor use only.	

## G1315B Diode Array Detector G1365B Multiple Wavelength Detector

### Performance Specifications

**Table 25** Performance Specifications Agilent 1200 Series DAD and MWD

Type	Specification	Comments
Detection type	1024-element photodiode array	
Light source	Deuterium and tungsten lamps	
Wavelength range	190 – 950 nm	
Short term noise (ASTM) Single and Multi-Wavelength	$\pm 1 \times 10^{-5}$ AU at 254 and 750 nm	See on page 52
Drift	$2 \times 10^{-3}$ AU/hr at 254 nm	See on page 52
Linear absorbance range	> 2 AU (upper limit)	See on page 52
Wavelength accuracy	$\pm 1$ nm	Self-calibration with deuterium lines, verification with holmium oxide filter
Wavelength bunching	1 – 400 nm	Programmable in steps of 1 nm
Slit width	1, 2, 4, 8, 16 nm	Programmable slit
Diode width	< 1 nm	
Flow cells	Standard: 13 $\mu$ l volume, 10 mm cell path length and 120 bar (1760 psi) pressure maximum Semi-Micro: 5 $\mu$ l volume, 6 mm cell path length and 120 bar (1760 psi) pressure maximum Micro: 2 $\mu$ l volume, 3 mm cell path length and 120 bar (1760 psi) pressure maximum High pressure: 1.7 $\mu$ l volume, 6 mm cell path length and 400 bar (5880 psi) pressure maximum 80 nano: 0.08 $\mu$ l volume, 10 mm cell path length and 50 bar (725 psi) pressure maximum 500 nano: 0.5 $\mu$ l volume, 10 mm cell path length and 50 bar (725 psi) pressure maximum	See <a href="#">“Optimization Overview”</a> .

## 2 Design Qualification (DQ) Phase

### Detectors Specifications

**Table 25** Performance Specifications Agilent 1200 Series DAD and MWD(continued)

Type	Specification	Comments
Control and data evaluation	Agilent ChemStation for LC	
Analog outputs	Recorder/integrator: 100 mV or 1 V, output range 0.001 – 2 AU, two outputs	
Communications	Controller-area network (CAN), GPIB, RS-232C, APG Remote: ready, start, stop and shut-down signals, LAN optional	
Safety and maintenance	Extensive diagnostics, error detection and display (through control module and ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.	
GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of lamp burn time with user-settable limits and feedback messages. Electronic records of maintenance and errors. Verification of wavelength accuracy with built-in holmium oxide filter.	
Housing	All materials recyclable.	

#### NOTE

ASTM: “Standard Practice for Variable Wavelength Photometric Detectors Used in Liquid Chromatography”.

Reference conditions: cell path length 10 mm, response time 2 s, flow 1 ml/min LC-grade Methanol, slit width 4 nm.

Linearity measured with caffeine at 265 nm.

For environmental conditions refer to “[Environment](#)” in the User Manual.

Physical Specifications

Table 26 Physical Specifications

Type	Specification	Comments
Weight	11.5 kg (26 lbs)	
Dimensions (width × depth × height)	345 × 435 × 140 mm (13.5 × 17 × 5.5 inches)	
Line voltage	100 – 240 VAC, ± 10 %	Wide-ranging capability
Line frequency	50 or 60 Hz ± 5 %	
Power consumption (G1315B/65B)	300 VA / 125 W / 427 BTU	Maximum
Ambient operating temperature	0 – 55 °C (32 – 131 °F)	.
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95%, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the detector
Safety standards: IEC, CSA, UL, EN	Installation category II, pollution degree 2. For indoor use only.	

## G1315C Diode Array Detector SL G1365C Multiple Wavelength Detector SL

### Performance Specifications

**Table 27** Performance Specifications Agilent 1200 Series DAD and MWD

Type	Specification	Comments
Detection type	1024-element photodiode array	
Light source	Deuterium and tungsten lamps	The UV-lamp is equipped with I.D. tag that holds lamp typical information.
Wavelength range	190 – 950 nm	
Short term noise (ASTM) Single and Multi-Wavelength	$\pm 0.8 \times 10^{-5}$ AU at 254 and 750 nm	See note on page 31
Drift	$0.9 \times 10^{-3}$ AU/hr at 254 nm	See note on page 31
Linear absorbance range	> 2 AU (upper limit)	See note on page 31
Wavelength accuracy	$\pm 1$ nm	Self-calibration with deuterium lines, verification with holmium oxide filter
Wavelength bunching	1 – 400 nm	Programmable in steps of 1 nm
Slit width	1, 2, 4, 8, 16 nm	Programmable slit
Diode width	< 1 nm	
Flow cells	Standard: 13 $\mu$ l volume, 10 mm cell path length and 120 bar (1760 psi) pressure maximum Semi-Micro: 5 $\mu$ l volume, 6 mm cell path length and 120 bar (1760 psi) pressure maximum Micro: 2 $\mu$ l volume, 3 mm cell path length and 120 bar (1760 psi) pressure maximum High pressure: 1.7 $\mu$ l volume, 6 mm cell path length and 400 bar (5880 psi) pressure maximum 500 nano: 0.5 $\mu$ l volume, 10 mm cell path length and 50 bar (725 psi) pressure maximum 80 nano: 0.5 $\mu$ l volume, 10 mm cell path length and 50 bar (725 psi) pressure maximum	See <a href="#">“Optimization Overview”</a> in the manual All flow cells are equipped with I.D. tags that hold cell typical information.

**Table 27** Performance Specifications Agilent 1200 Series DAD and MWD(continued)

Type	Specification	Comments
Control and data evaluation	Agilent ChemStation for LC (32-bit)	Revision B.01.03 or above
Analog outputs	Recorder/integrator: 100 mV or 1 V, output range 0.001 – 2 AU, two outputs	
Communications	Controller-area network (CAN), RS-232C, APG Remote: ready, start, stop and shut-down signals, LAN	
Safety and maintenance	Extensive diagnostics, error detection and display (through control module and ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.	
GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of lamp burn time with user-setable limits and feedback messages. Electronic records of maintenance and errors. Verification of wavelength accuracy with built-in holmium oxide filter.	
Housing	All materials recyclable.	

**NOTE**

ASTM: “Standard Practice for Variable Wavelength Photometric Detectors Used in Liquid Chromatography”.

Reference conditions: cell path length 10 mm, response time 2 s, flow 1 ml/min LC-grade Methanol, slit width 4 nm.

Linearity measured with caffeine at 265 nm.

For environmental conditions refer to “[Environment](#)” in the manual.

## Physical Specifications

**Table 28** Physical Specifications

Type	Specification	Comments
Weight	11.5 kg (26 lbs)	
Dimensions (width × depth × height)	345 × 435 × 140 mm (13.5 × 17 × 5.5 inches)	
Line voltage	100 – 240 VAC, ± 10 %	Wide-ranging capability
Line frequency	50 or 60 Hz ± 5 %	
Power consumption (G1315C/G1365C)	160 VA /160 W / 546 BTU	Maximum
Ambient operating temperature	0 – 55 °C (32 – 131 °F)	.
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95%, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the detector
Safety standards: IEC, CSA, UL, EN	Installation category II, pollution degree 2. For indoor use only.	

## G1362A Refractive Index Detector

### Performance Specifications

**Table 29** Performance Specifications Agilent 1200 Series Refractive Index Detector

Type	Specification	Comments
Detection type	Refractive Index	
Refractive index range	1.00 - 1.75 RIU, calibrated	
Measurement range	+/- 600 x 10 <sup>-6</sup> RIU	
Optical zeroing		via set screw
Optics temperature control	5 ° C above ambient to 55 ° C	
Sample cell	volume 8uL maximum pressure 5 bar (0.5Mpa) maximum flow rate 5mL/minute	
Valves	Automatic purge and automatic solvent recycle	
Volumes	Inlet port to sample cell 62uL, inlet port to outlet port 590uL	
Liquid contact materials	316 stainless steel, teflon and quartz glass	
pH range	2.3 - 9.5	
Performance specifications	Short term noise < +/- 2.5 x 10 <sup>-9</sup> RIU Drift < 200 x 10 <sup>-9</sup> RIU/hour	see note below this table
Time programmable parameters	polarity, peak width	
Detector zero	automatic zero before analysis	

**Table 29** Performance Specifications Agilent 1200 Series Refractive Index Detector  
(continued)

Type	Specification	Comments
Control and data evaluation	Parameter entry, signal display, on-line help and diagnostics with the Agilent 1200 Series Control Module. Optional PCMCIA card for method, sequence and logbook storage and transfer. Agilent ChemStation for LC PC based software for control and data evaluation.	
Analog outputs	Recorder/integrator: 100 mV or 1 V, output range selectable, one output	
Communications	Controller-area network (CAN), GPIB, RS-232C, LAN, APG Remote: ready, start, stop and shut-down signals	
Safety and maintenance	Extensive diagnostics, error detection and display (through control module and ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.	
GLP features	Early maintenance feedback (EMF) for continuous tracking of instrument usage with user-selectable limits and feedback messages. Electronic records of maintenance and errors. Automated operational qualification/performance verification (OQ/PV).	
Housing	All materials recyclable.	

**Table 29** Performance Specifications Agilent 1200 Series Refractive Index Detector (continued)

Type	Specification	Comments
Environment:	0 to 55 ° C constant temperature at <95% humidity (non-condensing)	
Dimensions:	180 mm x 345 mm x 435 mm (7 x 13.5 x 17 inches) (height x width x depth)	
Weight	17 kg (38 lbs)	

**NOTE**

Based on ASTM method E-1303-95 “Practice for Refractive Index Detectors used in Liquid Chromatography”.Reference conditions; optics temperature 35 ° C, response time 4 s, flow 1.0 mL/min LC-grade Water, restriction capillary, column compartment temperature 35 ° C, Agilent 1200 Series on-line vacuum degasser, pump and thermostatted column compartment. Instrument equilibrated for 2 hours.

**Physical Specifications**

**Table 30** Physical Specifications Agilent 1200 Series Refractive Index Detector

Type	Specification	Comments
Weight	17 kg (38 lbs)	
Dimensions (width × depth × height)	345 × 435 × 180 mm (13.5 × 17 × 7 inches)	
Line voltage	100 – 240 VAC, ± 10 %	Wide-ranging capability
Line frequency	50 or 60 Hz ± 5 %	
Power consumption	160 VA	Maximum
Ambient operating temperature	0 – 55 ° C (32 – 131 ° F)	

**2 Design Qualification (DQ) Phase**  
**Detectors Specifications**

**Table 30** Physical Specifications Agilent 1200 Series Refractive Index Detector(continued)

Ambient non-operating temperature	-40 – 70 ° C (-4 – 158 ° F)	
Rel. Humidity	< 95%, at 25 – 40 ° C (77 – 104 ° F)	Non-condensing
Operating altitude	Up to 2000 m (6500 ft.)	
Non-operating altitude	Up to 4600 m (14950 ft.)	For storing the detector
Safety standards: IEC, CSA, UL, EN	Installation category II, pollution degree 2	For indoor use only

# Fraction Collectors Specifications

## G1364B Fraction Collector preparative scale

### Performance Specifications

**Table 31** performance Specifications Agilent 1200 Series PREPARATIVE SCALE Autosampler (G1364B)

Type	Specification
trigger modes	Time slices, Peak (threshold, up- / downslope), Timetable (combination of time intervals and peak) and Manual trigger (supported only with G1323B Control Module) Agilent 1200 Series DAD/MWD detectors (G1315A/B/C, G1365 A/B/C), the Agilent 1200 Series fluorescence detector and the Agilent G1946C/D, G1956A/B LC-MSD are fully supported other detectors can be used but are not supported for fraction collection.
operating modes	Discrete fractions: default mode for all vessels. The flow is diverted to waste, while moving from one vessel position to the next vessel position Continuous flow: optional, available only when using well plates. It is possible to move from one well plate position to the next one without diverting the flow into the well plate to waste
Fraction capacities and trays	4 x well-plates full tray (MTP)* (for use with deep well plates, only) 2 x well-plates std. tray (MTP) (for use with deep well plates, only) + 10 x 2 ml vials* (+ 1 half tray) 100 x 2 ml in std. tray (+ 1 half tray)* 3 x 40 x 2 ml in half tray* 3 x 15 x 6 ml in half tray* Full tray with 40 test tubes (30 mm OD, max. height 100 mm, ~45 ml / tube) Full tray with 60 test tubes (25 mm OD, max. height 100 mm, ~25 ml / tube) Full tray with 126 test tubes (16 mm OD, max. height 100 mm, ~12 ml / tube) Full tray with 215 test tubes (12 mm OD, max. height 100 mm, ~7 ml / tube) Installed trays are automatically detected and identified. <b>For the with uncapped vials, tests tubes and well plates, only!</b>

## 2 Design Qualification (DQ) Phase

### Fraction Collectors Specifications

**Table 31** performance Specifications Agilent 1200 Series PREPARATIVE SCALE Autosampler (G1364B)(continued)

Type	Specification
test tube / plate sizes	Minimum 48 mm to 100 mm maximum
Maximum tube volume	ca. 45 ml
Maximum flow rate	100 ml / min (depending on viscosity and generated back pressure, max. 6 bar at the diverter valve)
Delay volumes [μl]	Fraction collector inlet to diverter valve: ~500 (typical, depends on length of the tubing) Diverter valve: ~15 Diverter valve to needle: ~110 Needle: ~5
Delay calibration sensor	Single wavelength absorbance detector working at 654 nm, consisting of a LED and a photo diode
Diverter valve	3/2 Diverter valve with low internal volume (15 μl), switching time < 100 ms, maximum operating pressure 6 bar
cooling	Optional (with additional G1330B), performance depending on ambient conditions and the volume of collected fractions
maximum capacity	3 fraction collectors in parallel plus one recovery fraction collector connected via 12-Position, 13-Port Selector valve (PN G1160A)
GLP features	Early maintenance feedback (EMF), electronic records of maintenance and errors
Interfaces	Controller-area network (CAN). optional; LAN or external contacts interface RS232C, APG-remote (for remote start / stop signals to / from other modules) Interface to G1330A Thermostat CAN-DC-out for operation of Agilent approved external devices like valves
Safety features	Leak detection and safe leak handling, error detection and display, exhaust fan for fume extraction of hazardous vapors

\* Vials can be used as recommended by Agilent Technologies (see “List of Recommended Vials and Caps” in the manual and “List of Recommended Plates and Closing Mats” in the manual) **but must be uncapped**. Only the 96 deep well-plates can be used (**without closing mats**, see “List of Recommended Plates and Closing Mats” in the manual)

**NOTE**

Only one type of well-plates can be used at a time in one tray.

## Physical Specifications

**Table 32** Physical Specifications - Autosamplers (G1364B, G1364C)

Type	Specification	Comments
Weight	13.5 kg (29.8 lbs)	
Dimensions (height × width × depth)	200 × 345 × 440 mm (8 × 13.5 × 17 inches)	
Line voltage	100 – 240 VAC, ±10 %	Wide-ranging capability
Line frequency	50 or 60 Hz, ±5 %	
Power consumption (apparent power)	200 VA	Maximum
Power consumption (active power)	180 W	Maximum
Ambient operating temperature	4 – 55 °C (41 – 131 °F)	
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	

**2    Design Qualification (DQ) Phase**  
**Fraction Collectors Specifications**

**Table 32**    Physical Specifications - Autosamplers (G1364B, G1364C)(continued)

Type	Specification	Comments
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the autosampler
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2. For indoor use only.	

## G1364C ANALYTICAL SCALE Fraction Collector

**Table 33** Performance Specifications Agilent 1200 Series ANALYTICAL SCALE Autosampler (G1364C)

Type	Specification
trigger modes	<p>Time slices, Peak (threshold, up- / downslope), Timetable (combination of time intervals and peak) and Manual trigger (supported only with G1323B Control Module)</p> <p>Agilent 1200 Series DAD/MWD detectors (G1315A/B/C, G1365 A/B/C), the Agilent 1200 Series fluorescence detector and the Agilent G1946C/D, G1956A/B LC-MSD are fully supported other detectors can be used but are not supported for fraction collection.</p>
operating modes	<p>Discrete fractions: default mode for all vessels. The flow is diverted to waste, while moving from one vessel position to the next vessel position</p> <p>Continuous flow: optional, available only when using the deep well plates. It is possible to move from one well plate position to the next one without diverting the flow into the well plate to waste</p> <p>Needle into location: Needle pushes into the vessel as deep as specified, for the use with capped vials and test tubes and well plates with closing mats</p> <p>Droplet setup mode: The tip of the fraction collector needle will initially move down to the bottom of the well. Then it will slowly move upwards while the fraction is collected. The droplet setup mode enables the fraction collector to collect small fractions without bubbles.</p>
fraction vessel capacities and trays	<ul style="list-style-type: none"> <li>• 4 x well-plates full tray (MTP)*</li> <li>• 2 x well-plates std. tray + 10 funnels with external containers* (+ 1 half tray)</li> <li>• 2 x well-plates std. tray (MTP) + 10 x 2 ml vials* (+ 1 half tray)</li> <li>• 100 x 2 ml in std. tray (+ 1 half tray)*</li> <li>• 3 x 40 x 2 ml in half tray*</li> <li>• 3 x 40 funnels in half tray</li> <li>• 3 x 15 x 6 ml in half tray*</li> <li>• Full tray with 40 test tubes (30 mm OD, max. height 48 mm, ~20 ml vol.)</li> <li>• Full tray with 60 test tubes (25 mm OD, max. height 48 mm)</li> <li>• Full tray with 126 test tubes (16 mm OD, max. height 48 mm)</li> <li>• Full tray with 215 test tubes (12 mm OD, max. height 48 mm)</li> </ul> <p>Installed trays are automatically detected and identified. Installed plates and vials can be detected when operating in the needle into location mode</p> <p>* max. height can be extended by using the short needle assembly G1364-87202</p>

**Table 33** Performance Specifications Agilent 1200 Series ANALYTICAL SCALE Autosampler (G1364C)(continued)

Type	Specification
maximum tube / plate height	48 mm with long needle assembly G1367-87200 75 mm with short needle assembly G1364-87202
Maximum tube volume	ca. 20 ml with 48 mm test tubes, ca. 30 ml with 75 mm test tubes or unlimited, if funnels are used with external containers.
Maximum flow rate	10 ml / min (depending on viscosity and generated back pressure, max. 6 bar at the diverter valve). The analytical scale fraction collector can be modified for flow rates > 10 ml/min.
delay volumes [μl]	Fraction collector inlet to diverter valve: ~50 (typical, depends on the length of the tubing) Diverter valve: ~15 Diverter valve to needle: ~10 Needle: ~4
delay calibration sensor	Single wavelength absorbance detector working at 654 nm, consisting of a LED and a photo diode
diverter valve	3/2 Diverter valve with low internal volume (15 μl), switching time < 100 ms, maximum operating pressure 6 bar
cooling	Optional (with additional G1330B), performance depending on ambient conditions and the volume of collected fractions
maximum capacity	3 fraction collectors in parallel plus one recovery fraction collector connected via 12-Position, 13-Port Selector valve (PN G1160A)
GLP features	Early maintenance feedback (EMF), electronic records of maintenance and errors
interfaces	- Controller-area network (CAN). - optional; LAN or external contacts interface - RS232C, - APG-remote (for remote start / stop signals to / from other modules) - Interface to G1330A Thermostat - CAN-DC-out for operation of Agilent approved external devices like valves
safety features	Leak detection and safe leak handling, error detection and display, exhaust fan for fume extraction of hazardous vapors

- \* Vials and well-plates and capped vials and well plates with closing mats can be used as recommended by Agilent Technologies (see [“List of Recommended Vials and Caps”](#) in the manual and [“List of Recommended Plates and Closing Mats”](#) in the manual)

**NOTE**

Only one type of well-plates can be used at a time in one tray.

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## G1364D Micro Collector/Spotter

### Performance Specifications

**Table 34** Performance Specifications Agilent 1200 Series Micro Autosampler (G1364D)

Type	Specification
trigger modes	Time slices, Peak (threshold, up- /downslope), Timetable (combination of time intervals and peak) and Agilent 1200 UV-Vis detectors DAD G1315A/B, MWD G1365 A/B are fully supported. Other detectors with appropriate delay volumes can be connected through UIB interface.
operating modes	Above location Into location Liquid Contact Control: The tip of the fraction collector capillary will initially move down to the bottom of the well. Then it will slowly move upwards while the fraction is collected. The contact control mode enables the micro collector/spotter to collect fractions down to 2 µl in well plates or MALDI spots down to 100 nl
fraction vessel capacities and trays	<ul style="list-style-type: none"> <li>• 4 well-plates full tray (MTP) with: 384 or 96-well plates (standard and conical shape) or 4 x 27, Eppendorf tubes (0.5, 1.5, 2.0 ml), MALDI Target Plates.</li> <li>• 2 x well-plates std. tray (MTP) + 10 x 2 ml vials (+ 1 half tray) with: 384 or 96-well plates (standard and conical shape) or 2x 27 eppendorf tubes (0.5, 1.5, 2.0 ml),</li> </ul>
MALDI Spotting plates (pre-configured)	<ul style="list-style-type: none"> <li>• 96 Agilent plate for AP-MALDI</li> <li>• 100 Applied Biosystems, 2x96 Applied Biosystems, 192 Applied Biosystems, 400 Perceptive Biosystems</li> <li>• Micromass 80/96 spots</li> <li>• Bruker Anchor Chips 384/1536 spots</li> </ul>
MALDI Plate Capacity	4 (3 for Bruker Anchor Chip 1536)
Minimum fraction volume	Typically 2 µl (depending on the fraction collection container)
MALDI spot size	100-5000 nl (depending on the MALDI plate)
maximum spotting rate	20 spots/min (1spot/3s)
Maximum flow rate	100 µl/min

**Table 34** Performance Specifications Agilent 1200 Series Micro Autosampler (G1364D)(continued)

Type	Specification
delay volumes [μl]	25 μm ID fraction collector capillary: ~0.25 50 μm ID fraction collector capillary: ~1 100 μm ID fraction collector capillary: ~5
cooling	Recommended (with additional G1330B)
maximum capacity	2 micro collector/spotter connected via 2-Position, 6-Port micro valve (G1162A)
GLP features	Early maintenance feedback (EMF), electronic records of maintenance and errors
interfaces	<ul style="list-style-type: none"> <li>- Controller-area network (CAN).</li> <li>- optional; LAN or external contacts interface</li> <li>- RS232C,</li> <li>- APG-remote (for remote start / stop signals to / from other modules)</li> <li>- Interface to G1330A Thermostat</li> <li>- CAN-DC-out for operation of Agilent approved external devices like valves</li> </ul>

**NOTE**

Only one type of well plate or MALDI plate can be used at a time in one tray.

## Physical Specifications

**Table 35** Physical Specifications - micro collector/spotter G1364D

Type	Specification	Comments
Weight	13.5 kg (29.8 lbs)	
Dimensions (height × width × depth)	200 × 345 × 440 mm (8 × 13.5 × 17 inches)	

## 2 Design Qualification (DQ) Phase

### Fraction Collectors Specifications

**Table 35** Physical Specifications - micro collector/spotter G1364D(continued)(continued)

Type	Specification	Comments
Line voltage	100 – 240 VAC, $\pm 10$ %	Wide-ranging capability
Line frequency	50 or 60 Hz, $\pm 5$ %	
Power consumption (apparent power)	200 VA	Maximum
Power consumption (active power)	180 W	Maximum
Ambient operating temperature	4 – 55 °C (41 – 131 °F)	
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the autosampler
Safety standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2. For indoor use only.	

# Valves Specifications

## G1157A Agilent 1200 Series 2 position / 10 port valve

### Performance Specifications

**Table 36** 2 position / 10 port valve

Liquid contacts	Stainless Steel and PEEK
Port size:	Accepts 10-32 male threaded fittings
Flow passage diameters:	Stator and stator face assembly 0.6-mm (0.024”), rotor seal 0.6-mm (0.024”)
Volume in flow passage:	Stator (includes stator face seal) 2.1 µl/hole, rotor seal 0.7 µl/groove
Maximum pressure:	41 MPa (408 bar, 6000 psi)
Recommended flow range:	0.2 - 100 ml/min

### Physical Spesificarions for all Valves

**Table 37** Physical Spesificarions for Agilent 1200 Series Valves

Type	Specification
• Weight	1.9 Kg (4.2 lbs)
• Dimensions • (height x width x depth)	92 x 84 x 200 mm (9.2 x 3.3 x 8.0 inches)
• Power supply	24 Volts DC (1.7 amps)
• Ambient operating temperature	4 to 55°C (39 to 131°F)
• Humidity	< 95%, non-condensing

**2 Design Qualification (DQ) Phase**  
**Valves Specifications**

**Table 37** Physical Specifications for Agilent 1200 Series Valves(continued)

Type	Specification
• Safety Standards	IEC, CSA, UL, EN Installation category II, pollution degree 2 For indoor use only
Revision	
• Agilent 1200 Firmware	A.05.04 and higher
• Control Module Firmware G1323B	B.03.11 and higher
• Agilent ChemStation Software	A.09.03 and higher

G1158A Agilent 1200 Series 2 position / 6 port valve

Performance Specifications

Table 38 2 position / 6 port valve

Liquid contacts:	Stainless steel, PEEK, and alumina ceramic
Port size:	Accepts 10-32 male threaded fittings
Flow passage diameters:	Stator and stator face assembly 0.4-mm (0.015”), rotor seal 0.5-mm (0.018”)
Volume in flow passage:	Stator (includes stator face seal) 0.7 µl/hole, rotor seal 0.3 µl/groove
Maximum pressure:	41 MPa (408 bar, 6000 psi)
Recommended flow range:	0.2 - 100 ml/min

**G1159A Agilent 1200 Series 6 position selection valve**

**Table 39**    6 position selection valve

Liquid contacts:	Stainless steel and PEEK
Port size:	Accepts 10-32 male threaded fittings
Flow passage diameters:	Stator 0.6-mm (0.024"), stator face assembly and rotor seal 0.4-mm (0.015")
Volume in flow passage	Angled ports 1, 2, 5 (15.6 µl) Radial ports 2, 4, 6 (18,8 µl)
Maximum pressure:	35 MPa (345 bar, 5000 psi)
Recommended flow range:	0.3 - 40 ml/min *

\*    The G1159A Agilent 1200 Series 6 positions selection valve can be used at flow rates up to 100 ml/min, but without valve switching. In most cases e.g. column selection the valve switches during the postrun or prerun, when the flow can be reduced.

G1160A Agilent 1200 Series 12 position/ 13 port selection valve

Table 40 12 position/ 13 port selection valve

Liquid contacts:	Stainless steel and PEEK
Port size:	Accepts 10-32 male threaded fittings
Flow passage diameters:	1.0-mm (0.040")
Volume in flow passage:	Stator (includes stator face seal) 6.4 µl/hole, rotor seal 4.0 µl/groove
Maximum pressure:	21 MPa (207 bar, 3000 psi)
Recommended flow range:	0.2 - 100 ml/min (at high pressures, after the pump) 0.2 - 10 ml/min (at low pressures, in front of the pump)

**G1162A Agilent 1200 Series 2 position/ 6 port micro valve**

**Table 41**    2 position/ 6 port micro valve

Liquid contacts:	DuraLife processed stainless steel (stator) and vespel (rotor seal)
Port size:	Accepts M4 male threaded fittings
Flow passage diameters:	0.20 mm (0.008")
Volume in flow passages:	70 nl port to port
Maximum pressure:	41 MPa (408 bar, 6000 psi)
Recommended flow range:	0.1 - 100 µl

G1163A Agilent 1200 Series 2 position/ 10 port micro valve(continued)

Table 42 2 position/ 10 port micro valve

Liquid contacts:	DuraLife processed stainless steel (stator) and vespel (rotor seal)
Port size:	Accepts M4 male threaded fittings
Flow passage diameters:	0.20 mm (0.008")
Volume in flow passages:	Stator (20° ports)27.2 nl, (45° ports) 30.5 nl, rotor seal 25.0 nl/groove
Maximum pressure:	41 MPa (408 bar, 6000 psi)
Recommended flow range:	0.1 - 100 µl

# Miscellaneous Specifications

## G1322A Vacuum Degasser

### Performance Specifications

**Table 43** Performance Specifications Agilent 1200 Series Vacuum Degasser

Type	Specification
Maximum flow rate	10 ml/min per channel
Number of channels	4
Internal volume per channel	Typically 12 ml per channel
Materials in contact with solvent	PTFE, PEEK
pH range	1 – 14
Analog output (AUX)	For pressure monitoring, range 0 – 3 V

### NOTE

The G1322 Vacuum Degasser has been tested for evaporation of solvents into the atmosphere by an independent institute with approved methods. The tests were performed with Methanol (BIA Nr. 7810) and Acetonitrile (NIOSH, Nr. 1606). Evaporation of these solvents into the atmosphere when operating the degasser was below the limits of detection.

### Physical Specifications

**Table 44** Physical Specifications

Type	Specification	Comments
Weight	7 kg (15.4 lbs)	

**Table 44** Physical Specifications(continued)

Dimensions (width × depth × height)	345 × 435 × 80 mm (13.5 × 17 × 3.1 inches)	
Line Voltage	100 – 120 or 220 – 240 VAC, ± 10 %	Wide-ranging capability
Line Frequency	50 or 60 Hz, ± 5 %	
Power consumption	30 W	Maximum
Ambient Operating Temperature	0 – 55 °C (32 – 131 °F)*	see <i>User manual</i>
Ambient Non-operating Temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	
Non-operating Altitude	Up to 4600 m (14950 ft)	For storing the instrument
Safety Standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2	

\* This temperature range represents the technical specifications for this instrument. The mentioned temperatures may not be suitable for all applications and all types of solvents.

**WARNING**

**Never operate your instrumentation under conditions other than specified by the vendor. Operating the instrumentation under conditions other than their intended use might result in a potential safety hazard or might damage the instrumentation.**

# G1379B Micro Vacuum Degasser

## Performance Specifications

**Table 45** Performance Specifications Agilent 1200 Micro Vacuum Degasser

Type	Specification
Maximum flow rate	0 - 5 ml/min per channel
Number of channels	4
Internal volume per channel	Typically 1 ml per channel
Materials in contact with solvent	PTFE, FEP,PEEK
pH range	1 – 14
RS-232 output	For diagnostic purposes

**NOTE**

The Agilent 1200 Series micro vacuum degasser has been tested for evaporation of solvents into the atmosphere by an independent institute with approved methods. The tests were performed with Methanol (BIA Nr. 7810) and Acetonitrile (NIOSH, Nr. 1606). Evaporation of these solvents into the atmosphere when operating the degasser was below the limits of detection.

## Physical Specifications

**Table 46** Physical Specifications

Type	Specification	Comments
Weight	7 kg (15.4 lbs)	
Dimensions (width × depth × height)	345 × 435 × 80 mm (13.5 × 17 × 3.1 inches)	
Line Voltage	100 – 120 or 220 – 240 VAC, ± 10 %	Wide-ranging capability
Line Frequency	50 or 60 Hz, ± 5 %	

**Table 46** Physical Specifications(continued)

Power consumption	30 W	Maximum
Ambient Operating Temperature	0 – 45 °C (32 – 113 °F) *	see <i>User manual</i>
Ambient Non-operating Temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing
Operating Altitude	Up to 2000 m (6500 ft)	
Non-operating Altitude	Up to 4600 m (14950 ft)	For storing the instrument
Safety Standards: IEC, CSA, UL	Installation Category II, Pollution Degree 2	for indoor use only!

\* This temperature range represents the technical specifications for this instrument. The mentioned temperatures may not be suitable for all applications and all types of solvents.

## G1316A Thermostatted Column Compartment G1316B Thermostatted Column Compartment

### Performance Specifications

**Table 47** Performance Specifications Agilent 1200 Series Thermostatted Column Compartment G1316A/G1316B

Type	Specification	Comments
Temperature range	10 degrees below ambient to 80 °C	G1316A
	10 degrees below ambient to 100 °C	G1316B (SL)
	up to 80 °C: flow rates up to 5 ml/min up to 100 °C: flow rates up to 2.5 ml/min	G1316A / G1316B (SL) G1316B (SL)
Temperature stability	± 0.15 °C	G1316A
	± 0.05 °C	G1316B (SL)
Temperature accuracy	± 0.8 °C	
	± 0.5 °C	With calibration
Column capacity	Three 30 cm	
Warm-up/cool-down time	5 minutes from ambient to 40 °C	
	10 minutes from 40 – 20 °C	
Dead volume	3 µl left heat exchanger	i.d. 0.17 mm
	6 µl right heat exchanger	
Dimensions (h × w × d)	140 × 410 × 435 mm	
	(5.5 × 16 × 17 inches)	
Weight	10.2 kg (22.5 lbs)	
Communications	Controller-area network (CAN), GPIB, RS-232C, APG Remote: ready, start, stop and shut-down signals, LAN via other 1200 series module	no GPIB on G1316B SL
Safety and maintenance	Extensive diagnostics, error detection and display (through control module and Agilent ChemStation), leak detection, safe leak handling, leak output signal for shutdown of pumping system. Low voltages in major maintenance areas.	

**Table 47** Performance Specifications Agilent 1200 Series Thermostatted Column Compartment G1316A/G1316B(continued)

Type	Specification	Comments
GLP features	Column-identification module for GLP documentation of column type, see <a href="#">“Column-Identification System”</a> in the manual	
Housing	All materials recyclable.	

**NOTE**

All specifications are valid for distilled water at ambient temperature (25 °C), set point at 40 °C and a flow range from 0.2–5 ml/min.

**Physical Specifications****Table 48** Physical Specifications

Type	Specification	Comments
Weight	10.2 kg (22.5 lbs)	
Dimensions (width × depth × height)	410 × 435 × 140 mm (16.1 × 17 × 5.5 inches)	
Line Voltage	100 – 240 VAC, ± 10 %	Wide-ranging capability
Line frequency	50 or 60 Hz, ± 5 %	
Power consumption	320 VA / 150 W / 512 BTU	Maximum
Ambient operating temperature	0 – 55 °C (32 – 131 °F)	
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	<95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing

**2    Design Qualification (DQ) Phase**  
**Miscellaneous Specifications**

**Table 48**    Physical Specifications(continued)

Operating altitude	Up to 2000 m (6500 ft.)	
Non-operating altitude	Up to 4600 m (14950 ft.)	For storing the instrument
Safety standards: IEC, CSA, UL, EN	Installation Category II, Pollution Degree 2 For indoor use only.	

G1330A Autosampler Thermostat

Performance Specifications

Table 49 Performance Specifications Agilent 1200 autosampler thermostat

Type	Specification
Temperature range:	setable from 4°C to 40°C in 1° increments
Temperature accuracy at ambient temperatures < 25°C and humidity < 50%	-1°C to +4°C at a setpoint of 4°C
Temperature accuracy at ambient temperatures > 25°C and/or humidity > 50%	-1°C to +5°C at a setpoint of 4°C

Physical Specifications

Table 50 Physical Specifications - Thermostatted Autosampler

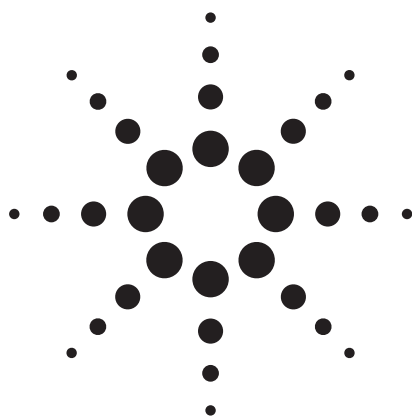
Type	Specification	Comments
Thermostat Weight	20.7 kg (45.6 lbs)	
Dimensions (height × width × depth)	140 × 345 × 435 mm (5.5 × 13.5 × 17 inches)	
Line voltage	100 – 120 or 220 – 240 VAC, ± 10 %	Automatic selection
Line frequency	50 or 60 Hz, ± 5 %	
Power consumption	Autosampler: 300 VA ALS Thermostat: 260 VA	Maximum Maximum
Ambient operating temperature	4 – 40 °C (41 – 131 °F)	see <i>User manual</i>
Ambient non-operating temperature	-40 – 70 °C (-4 – 158 °F)	
Humidity	< 95 %, at 25 – 40 °C (77 – 104 °F)	Non-condensing;
Operating Altitude	Up to 2000 m (6500 ft)	

**2 Design Qualification (DQ) Phase**  
**Miscellaneous Specifications**

**Table 50** Physical Specifications(continued)- Thermostatted Autosampler(continued)

Type	Specification	Comments
Non-operating altitude	Up to 4600 m (14950 ft)	For storing the autosampler
Safety standards: IEC, CSA, UL, EN	Installation Category II, Pollution Degree 2	

## **Agilent ChemStation Specifications**



# Agilent ChemStation for GC, LC, LC/MSD, CE, and A/D Systems - Rev. B.02.01

## Specifications

May 2006

### What's New in Rev

Revision B.02.01 is the newest version in active development of Agilent ChemStation. Its new User Interface addresses customer's growing needs for faster acquisition and review of data. A modern tree view along with a new navigation table allows easy finding, sorting and review of multiple sample data. It adopts new Microsoft technologies while maintaining well known ChemStation concepts to avoiding need of re-training.

*Note: Rev. B.02.01 Agilent ChemStation software release does not relate to UV-VIS or GC/MSD instrumentation. These instruments are controlled and supported by separate Agilent ChemStation software products.*

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- New and improved ChemStation User Interface design
- New tree- and table based navigation providing fast and flexible Data Handling within various ChemStation views
- Improved data review and reprocessing capabilities using the Data Analysis Navigation Table
- Flexible storage locations for data, methods, and sequences
- New packaging concept for sequence data guarantees consistency of all methods and results within a sequence
- Additional signal options give possibility to assign method

- New signal options to improve data review
- Ability to save manual integration events in Data Analysis method along with newly acquired sequence data files
- Online help integrated ChemStation tutorial, to enable learning the software while working on your own methods and data
- Enhanced utilization of high resolution monitor and available screen real estate

For users of the Agilent 1100 /1200 Series LC systems and LC software:

- Support for the GPC Add-on software G2182BA
- Direct software link to new Agilent LC Diagnostics
- Interface for 3rd party LC detector drivers



Agilent Technologies

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Introduction and full support of the new Agilent 1200 Series LC, including the new Agilent 1200 Series Rapid Resolution LC system with the following new hardware modules:

- Agilent 1200 Series binary pump SL (G1312B)
- Agilent 1200 Series high performance autosampler SL (G1325C)
- Agilent 1200 Series thermostated column compartment (G1316B)
- Agilent 1200 Series variable wavelength detector SL (G1315C)
- improved diode-array detector SL (G1315C)
- improved Agilent 1200 multiple wavelength detector (G1365C)

**For users of the GC systems and GC software**

- With B.02.01, a GC column database utility is available to transfer user-defined GC columns after an upgrade from G2070AA to G2070BA ChemStation. The utility is available on the ChemStation CD-ROM in the Support directory.

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*Important firmware information for Agilent 1200/1100 Series systems:*

- For Agilent 1200/1100 Series modules the minimum firmware revision is A.06.02
- The new G1315C/G1356C DAD-SL/MWD-SL require firmware B.01.02.
- Firmware Rev. A.06.02 and B.01.02 are *not* compatible with 6.01 resp. B.01.01 or earlier.

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## General Description

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The Agilent 32-Bit ChemStations for GC, LC, LC/MSD, CE and A/D systems are instrument control, data acquisition and data evaluation systems for:

- Agilent 6890N, 6890 Plus and 6890A gas chromatographs,
- Agilent 6850 gas chromatograph,
- Agilent 5890 Series II and 4890D gas chromatographs,
- Agilent 1200 Series modular and systems for HPLC, including the Agilent 1200 Series LC/MSD,
- Agilent 1100 Series modular and systems for HPLC, including the Agilent 1100 Series LC/MSD,
- HP 1090 Series liquid chromatographs,
- Agilent 35900E dual channel analog-to-digital interface, and
- Agilent capillary electrophoresis systems.

The software is designed to run on IBM compatible personal computers with a PCI interface under Microsoft Windows operating environments.

### Core ChemStation 2D Software

Five core 32-Bit ChemStation 2D software products are available. Each core software product provides data acquisition, instrument control, data analysis (integration, quantification and reporting),

automation and customization for a single analytical instrument. A single instrument may collect data from a number of different detectors simultaneously. The fivecore 2D software products are:

- Agilent 32-Bit ChemStation for 2D Liquid Chromatography (LC) systems (G2170BA)
- Agilent 32-Bit ChemStation for

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Converter (A/D) systems,  
(G2072BA)

### ChemStation 3D Software Module

The capabilities of the core 2D LC software may be expanded to allow for 3D data through the purchase of the additional LC 3D Spectral Module (G2180BA).

### ChemStation Additional Instrument Control Software

The instrument control capabilities of the core Agilent ChemStation software may be extended to allow for multiple instrument systems by purchasing

additional instrument control software. It is possible to configure up to four chromatography instruments per ChemStation PC. The four additional instrument control software products are:

- Additional LC Instrument Control and Data Acquisition software, (G2171BA)
- Additional GC Instrument Control and Data Acquisition software, (G2071BA)
- Additional LC/MS Instrument Control and Data Acquisition software, (G2073BA)
- Additional CE Instrument Control and Data Acquisition software module (G2074BA)
- Additional A/D Converter software (G2201BA) for G1946X
- Additional 35900E Analog to Digital Converter (A/D) Instrument Control and Data Acquisition software (G2073BA)

### ChemStation License to use software on another PC

Once an initial core ChemStation software product has been purchased it is possible to purchase licenses to use that software on another PC. The available license products are:

- License to use 2D LC ChemStation software on another PC (G2175BA)

- License to use 3D LC ChemStation software on another PC (G2185BA)
- License to use GC ChemStation software on another PC (G2075BA)
- License to use CE ChemStation software on another PC (G2205BA)
- License to use A/D ChemStation software on another PC (G2077BA)

#### ChemStation Data Analysis Only Software

There are three data analysis ChemStation software products. These products are for data evaluation only and are not for use as an example in an office setting and should not have been configured. The three products are software products.

- ChemStation Data Analysis software for LC (G2190BA)
- ChemStation Data Analysis software for GC (G2090BA)
- ChemStation Data Analysis software for LC/MSD (G2730BA)

#### ChemStation Plus Add-On Software Modules

Agilent provides a range of add-on software modules which extend the capabilities of the ChemStation base software. The modular architecture ensures that you can control your enhanced system from the same, familiar user interface. ChemStation Plus is a fully scalable solution that enables you to expand your data system from single PC to instrument con-

figurations right through to distributed, multi-technique configurations and client-server functionality. Users, instruments and applications can be added without disruption.

*Note: Some combinations (marked with\*) require ChemStation B.02.01 SR1.*

- **Agilent ChemStore, Standalone/Client\* (G2181BA) ChemStore Server\* (G1410A)**

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**Security Pack, (G2189AA)**  
Compliance with regulatory guidelines such as the FDA's 21 CFR Part 11

#### Dedicated Solutions for Specific Applications

- **High Throughput Purification (Purify) software modules\***  
Advanced, high-capacity preparative LC for large numbers of samples.
- **Agilent ChemStation Companion**  
Provides a simple single-screen user interface for GC routine analysis. Automatically installed with ChemStation GC software.

- **Retention Time Locking (G2080BA)**

Retention Time Locking software for the G2070BA GC ChemStation.

- **Integrated Headspace Control Software (G2924AA)**

Requires G2070BA GC ChemStation software.

- **Analyst Software (G2731AA)**

For LC/MSD data analysis.

Requires LC/MSD ChemStation software.

#### Peptide Tools (G2720AA)

LC/MSD Deconvolution & Analysis SW. For determination of molecular weight from multiply charged API-ES mass spectra & for evaluation of MS data from proteins/peptides/oligonucleotides.

Requires G2710BA LC/MSD ChemStation Software or G2715BA LC/MSD Add-on Software module to operate.

- **TOF Software (G3300AA)**

For CE-MS TOF.

## Computer Hardware

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The 32-Bit ChemStation consists of Hewlett-Packard personal computer hardware and ChemStation software. The hardware is an IBM compatible personal computer with an ISA or PCI interface bus.

The personal computer is interfaced to the analytical instruments through a LAN card, a GPIB card, a USB/GPIB interface card, or a combination of one GPIB card and a LAN card. All cards plug directly into the computer's PCI or interface. Third-Party instruments can be connected to the Agilent 35900E A/D-Converter interface. The separate hardware components that comprise the particular instrument configuration, including third party instrumentation, may need to be coordinated through a remote cabling system

for time critical events such as injection.

### **Non HP / Compaq Computers**

The Agilent ChemStation has been designed to successfully run on a wide range of compatible personal computers equipped with accessories and peripherals

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and EVO computers and may not be optimized for other vendor's PCs. The standard configuration

of the GPIB interface, for instance, may conflict with the memory configuration of a non-HP /Compaq computer. Additional accessory interface boards may cause conflicts of hardware related resources (I/O ports, interrupt settings, DMA channels). For a non-HP/

computer, use the setup program supplied by the manufacturer to configure your system and check the supplied documentation to eliminate conflicts in your PC's configuration, especially regarding the configuration of the GPIB interface. Although the software is designed to be run on other hardware Agilent

Technologies will not necessarily accept responsibility for defects solely observed and reported on third party hardware.

## Minimum PC Configuration

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### **Windows XP and Windows 2000 based systems:**

- Hewlett-Packard / Compaq PC with Pentium V, 1.5 GHz
- SXGA display (1280x1024 resolution)
- 40 GB hard disk

- MS Windows compatible pointing device
- ATAPI CD, CD-RW or DVD drive
- 10/100 baseT LAN interface card.

### **Minimum memory specifications:**

- 512 MB RAM

\* Agilent supports the use of hyperthreading on Pentium IV or higher PC's running Windows® XP.

## Maximum Number of Supported Instruments

---

A maximum of four instruments may be configured per Agilent ChemStation PC. The following instrument/module specific limitations exist:

- A maximum of two diode-array detector instruments may be configured per PC.
- A maximum of one variable wavelength detector (VWD), one pump module, one autosampler module, one thermostated component (TCC) module per instrument.
- A maximum of three instruments are supported per PC when ChemStore is installed.
- A maximum of three instruments are supported per PC when spectroscopy instruments are configured.
- An Agilent 1200/1100 Series LC/MSD system only allows one additional Agilent 1200/1100 or 1090 Series II HPLC instrument.
- CE ChemStation can co-reside with a second system (either LC or CE ChemStation), however coexecution of the software is not supported.

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## Maximum Number of Modules

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The guideline for the maximum number of modules that may be configured per Agilent ChemStation PC is 18. Approximately 12 analytical modules can be configured but this depends on the exact configuration.

*Note: Please contact your Agilent Technologies representative to confirm whether configurations approaching this 12 module limit are possible.*

Out of these 18 modules up to six CAN-slave modules can also be configured, e.g. valves or UIB interfaces. For correct configuration of specific instruments and modules please contact your Agilent Technologies representative. The ChemStation Plus Ordering Guide provides additional details on supported configurations.

## IEEE-488 GP-IB Support Matrix

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### Instruments Supported on GP-IB

Agilent 6890 Gas Chromatograph  
Agilent 5890 Gas Chromatograph  
Agilent 1090 Series LC systems  
Agilent Capillary Electrophoresis (CE)  
Agilent Capillary Electrophoresis Mass Spectrometry (CE/MS)  
HP 1046 FLD  
HP 1049 ECD  
HP 1090 LC

### 82350A/B GP-IB Interface Cards

Analytical instruments can communicate with the Agilent ChemStation via GPIB using a GPIB board installed in the computer. Agilent 82350A or 82350B PCI high-performance GPIB interface cards can be used on

cards a PCI slot is required on the PC. The Agilent 82350 is a PCI GPIB interface card and no additional settings such as changing the I/O base address are required. Please note that GPIB communication requires installation of the SICL I/O library version M.01.01. Please ask your local Agilent Technologies representative for details.

### USB/GP-IB Interface

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#### Instruments supported on USB/GP-IB (USB port or used):

- Agilent Capillary Electrophoresis (CE)
- Agilent Capillary Electrophoresis Mass Spectrometry (CE/MS)
- HP 1046 FLD
- HP1049 ECD
- HP 1090 LC

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from the USB port only on 1000 and 2000 series GPIB instruments. The interface is small, portable, flexible, uses industry standards and is easy to connect. The interface can be used on both Windows 2000 and Windows XP Professional systems. The USB/GPIB cable is available as an option against the

module (G1602BA Option 001) or as an internal support part (G1602BA Option 002) from the Support Center. Please ask your local Agilent Technologies representative for additional details.

*Note: USB/GPIB interfaces are only supported with legacy LC and CE instruments.*

## LAN-MIO Support Matrix

### G1369A Agilent LAN Interface Card

The firmware of the card must be revision A.01.05 or higher. For non-LC systems (35900E ADC, 6890 GC and 6850 GC) a minimum Firmware Revision of C.03.00 is required. Please refer to Service Note G1369-003.

### J2552B/C JetDirect Internal Printer Servers (MIO)

The firmware of the JetDirect card has to be revision A.08.32 or higher.

### J4100A JetDirect Network Printer Servers (MIO)

The firmware of the JetDirect card has to be revision K.08.00 or higher.

*Note:*

- The 6890N requires revision N.05.04 or higher. LAN board firmware revision 04.7B3. LAN communication with the Agilent 6890A requires firmware revision A.03.08 or higher. This is available in an electronic chip format from Agilent Technologies (Please ask your local Agilent Technologies representative for details).
- LAN communication with the Agilent 1100 Series requires a minimum firmware revision of A.06.02. The G1315C DAD-SL and G1356C MWD-SL detectors require a minimum firmware

revision of B.01.02. A new LAN/RS-232 Firmware Update Tool 2.1 is available for updating firmware quickly and easily. Please ask your local Agilent Technologies representative for details.

*Note: Firmware Rev. A.06.02 & B.01.02 are NOT compatible with Rev. A.06.02 & B.02.01 or earlier.*

### Instruments / Modules Supported on LAN

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LAN interface cards are used to connect analytical instruments to the LAN. Jet Direct or G1369A LAN cards are required. The minimum firmware required for LC systems used with the G1369A LAN card is Rev. A.01.05 or higher. For non-LC systems (35900E ADC, 6890 GC and 6850 GC) a minimum Firmware Revision of C.03.00 is required. Additional details are available in the Agilent G1369A LAN Interface manual.

### Communication Protocols

Instruments are controlled over LAN using industry standard TCP/IP (Transmission Control Protocol / Internet Protocol). It is necessary to verify correct communication between the PC and analytical instruments connected over the LAN. The Microsoft TCP/IP protocol needs to be installed and configured as a network protocol on the PC.

The boot strap protocol is used to configure the JetDirect or G1369A card. The Boot strap protocol requires a BootP service (see the readme). Agilent now supports the BootP service. The Agilent BootP Service Program uses the LAN communication parameters specified in the Configuration Editor to establish communication. The BootP Service Program can be used for central administration and distribution of IP addresses and settings.

### Fixed IP Addresses for Communication

IP addresses can be stored in the non-volatile RAM of the module's LAN card. Depending on the LAN card it is possible to assign a fixed IP address to the Agilent 1200/1100 Series modules, using either a handheld control module, a mode selecting a predefined address by DIP switch or Telnet to assign IP addresses. It is possible to assign a fixed IP address to the 6890N and 6850 using the front display.

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### **Additional Hardware Required for LAN Instrument Control**

An industry standard LAN PC card is shipped with all Agilent ChemStation 32-Bit PC bundles.

An instrument LAN card can also be ordered from Agilent Technologies as an option to the instrument or as an individual part. Please ask your Agilent Technologies representative for details.

Industry standard LAN using twisted pair or cabling:

- Twisted pair –10/100 twisted pair cabling connectors can be u

er with an Agilent G2402A 8-port 10/100 auto sensing switch for the ability to connect one or more instrument to a PC. A twisted pair 'crossover' cable can be used to make a single connection from one PC to one instrument. This configuration is only suitable for single instrument configurations. This configuration is not supported on Agilent 1200/1100 Series LC/MSD systems.

### **LAN Transmission Rates**

Traffic on the LAN from each instrument is approximately 100KB per second for a 2D instrument at maximum data rate.

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## **Printers**

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The Agilent ChemStation has been designed to work with printers that are compatible with the operating system. The software operates with any Microsoft Windows compatible printer capable of interpreting an escape code language (e.g. PCL) or page description language (e.g. PostScript). The printer may be directly connected to the computer through a parallel or serial interface or connected through a Local Area Network. Serial port printers are supported by the operating system but may exhibit speed performance limitations.

Networked printers must be shared by a network server running a network protocol supported by the Microsoft operating system.

Recommended black and white printers are the HP LaserJet family using PCL 5e or 6. For lower performance applications it is possible to use the HP DeskJet family. Please note that the HP DeskJet printer family is not recommended for high throughput applications.

Recommended color printers are the HP LaserJet 2500TN, OfficeJet Pro K550DTWN or an HP DeskJet family printer.

Agilent Technologies has not tested all printer and printer driver combinations that are supported in the Windows environment. Print performance and results may vary on other manufacturer's printers and appropriate drivers. Please note that host-based printers (e.g. GDI or PPA printers) impose more processing tasks on the CPU and are not recommended for use with the Agilent ChemStation on-line sessions.

## Operating System

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The Agilent 32-Bit ChemStation requires Microsoft Windows 2000 Professional with Service Pack 4

or Windows XP Professional with Service Pack 2.

## Methods and Sequences

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The Agilent ChemStation analytical method fully describes how a particular separation is performed. It contains all the parameters for instrument control, data acquisition and evaluation, including

integration, quantification and reporting. The system may be set up to acquire data from a number of samples by different methods. The control file for this operation is called a sequence and holds the

individual sample information, as well as references to the appropriate methods, user for data acquisition, data analysis and automatic recalibration specifications.

## System Configuration

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The configuration of the instrument system is done through the configuration editor program.

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ences and methods, and definition for the acquisition software.

## Data Model

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The ChemStation software is designed around a data model based on a memory structure called a register. Registers are multi-purpose structures that can hold analytical data and information for both two dimensional (e.g., time/intensity) and three dimensional (e.g. time/intensity/wavelength) analyses.

The ChemStation provides, commands and functions to construct, expand, extract and, where it does not alter primary data, edit registers.

Registers hold information about their contents in register headers. The registers are further subdivided into one or more objects. Typically an object holds data that describes an analytical measurement, such as a chromatography signal. Each of these objects

surement such as the data file name, injection date and time, sample name, and tables. Tables are used to hold different types of data as one block of information. For example, the quantification process in a calibrated method constructs a quantification table that contains peak numbers, compound names, compound amounts and retention times.

Like other parts of the registers, tables may be user-defined and have the functionality of database tables with the additional benefit of being directly associated with the base piece of analytical information from which they were derived.

Each register may hold informa-

different purposes. As analytical data, the register data model is used for holding configuration information and analytical methods. They may be saved as files on non-volatile storage and reloaded into the ChemStation memory, printed and plotted to the screen or a hard-copy device. Their binary format means they are not editable outside the ChemStation and each data item may also be protected by assigning access attributes to it when it is created.

Their design fits extremely well to modern database technology enabling systems to be developed to map analytical results or data directly to a relational database system.

## Software User Interface

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The Agilent ChemStation user interface consists of a navigation pane containing the ChemStation explorer plus navigation buttons and a navigation table. Both frame the Views that group software functionality according to typical analytical tasks. The ChemStation explorer provides means to select data or actions meaningful to the actual view, e.g. loading a sequence or method. Three standard views are present in all software configurations:

- The *Method and Run Control* view for controlling and acquiring data from the instrument.
- The *Data Analysis* view for reviewing data that has been acquired.
- The *Report Layout* view for designing reports.

The configuration options allow for customizing the views. Additionally, the user can select if additional modules have been installed. Certain instrument configurations support instrument diagnostics and verification procedures. The ChemStation Companion view offers an easy to use interface specifically designed for the production operator and routine labs. Instrument operators can run samples from an easy to use, preconfigured table.

Each view consists of a set of standard user elements including menus and toolbars.

The standard toolbar provides rapid access to the common system specification information such as methods and sequences.

The *Method and Run Control* view additionally incorporates a system status bar, a sample information area, that may be configured for single runs or automated runs, and a schematic instrument interface diagram for GC, LC, LC/MSD, CE and CE/MSD configurations. The schematic instrument interface diagram uses hot spots to allow rapid access to instrument parameters and an animated graphical overview of the status of

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analysis tasks including integration, calibration, reporting, reprocessing, annotation, signal comparison and additional specialized tasks if the appropriate modules are installed. Each of these separate data analysis modes are supported with a task-specific toolbar of its own.

The *Report Layout* view allows the user to graphically define the layout of a specific report style in a graphical object orientated fashion. It too uses a set of toolbars specific to this task.

## Data Acquisition

---

The status of the instrument is continually monitored and updated on the display, along with the elapsed run time of the analysis, both when the software is a visible window and when it is iconized. The transactions that occur during the analysis, including any errors and the instrument conditions at the start and end of the analysis, are recorded in the system's logbook, an example of which is stored with every file.

The instrument conditions, such as flow, temperature, pressure, solvent composition for liquid chromatographs may be recorded and stored with each data file.

These instrument parameters can be displayed and plotted to testify to the quality of each analysis. The exact nature of the parameters recorded depends both on the technique and the capabilities of the configured instrument.

One or more display windows may be used to monitor the data being acquired by the instrument in real time. The data are displayed in real measurement units such as mAU, Volts, degrees or bar. The windows may each show multiple overlaid chromatographic signals or instrument parameters, such as pressure. The display default settings may be adjusted and are remembered by the system so users can set their own

preferred settings as the instrument default. The window has zoom capability and the cursor may be used to display a specific signal's response at any point in time.

The complete functionality of the ChemStation can be used during

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the components of the schematic instrument interface diagram, is saved automatically.

## Data Analysis - Display

---

The data analysis view extends the standard tool bar with task-grouped data analysis functions including integration, calibration, reporting, annotation and signal comparison toolsets. Together with the navigation table they form a fast and powerful means for data review and reprocessing. The following key graphical operations are possible:

- Single or multi-signal displays selectable when loading the chromatogram
- Overlays of chromatograms from different files
- Subtraction of one chromatogram from another
- Graphical vertical alignment of multiple visual comparisons
- Signal inversion to help visual comparison.
- Graphical zoom and scrolling functions.
- Adjustment of display attributes including selection of tick marks, baselines, axes, retention times and compound names. The user can also select

the font for the RT and compound labels, adjust the size and orientation of the display, select the display as overlaid or separated and select scaling factors.

- The chromatogram display may include graphical overlays of instrument parameters depending on the capability of the configured instrument.
- User defined annotations may

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the values of individual data points in detector units.

- Export of time/intensity digitized points to the Microsoft Windows clipboard.
- Display of fraction results in graphics and table format



brated compound prepared in the calibration standards. If the origin is included it is assigned the mean of the weightings of the other calibration points.

**Linear (Resp)** – A calibration point with the response  $y$  has the weighting  $1/y$  normalized to the smallest response so that the largest weight factor is 1. Normalization is done by multiplying the weight with the smallest response. For example the weight of a calibration point with the amount  $y$  is  $(1/y) \times b$  where  $b$  is the response corresponding to the smallest amount of the calibrated compound prepared in the calibration standards. If the origin is included it is assigned the mean of the weightings of the other calibration points.

**Quadratic (Amnt)** – A calibration point with the amount  $x$  has the weighting  $1/x^2$  normalized to the smallest amount so that the largest weight factor is 1. Normalization is done by multiplying the weight with the smallest amount. For example the weight of a calibration point with the amount  $x$  is  $(1/x^2) \times a^2$  where  $a$  is the smallest amount of the calibrated compound prepared in the calibration standards.

**Quadratic (Resp)** – A calibration point with the response  $y$  has the weighting  $1/y^2$  normalized to the smallest response so that the largest weight factor is 1. Normalization is done by multiplying the weight with the smallest

response. For example the weight of a calibration point with the response  $y$  is  $(1/y^2) \times b^2$  where  $b$  is the response corresponding to the smallest amount of the calibrated compound prepared in the calibration standards.

**# Calibrations** – A calibration point is weighted according to the number of recalibrations of the point. No normalization is done.

The origin of the calibration curve may be specified as

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Compound identification may be refined by defining individual retention time windows' parameter limits and qualifier peaks. Qualifier peaks are usually the same compound detected on a different signal with a predictable response ratio. They are used as a further check on peak identification rather than just relying on retention times.

Each calibrated compound may have individual absolute limits for the amount, peak area, peak height, symmetry, efficiency in plates, resolution and  $k'$ . Results lying outside any defined limits

are indicated on the appropriate analysis report. They may be used in conjunction with the control samples that can be defined as part of the automation setup, to verify the performance of the system running automatically.

The ChemStation can calibrate methods with up to 1000 peaks and 2000 calibration points. This means, for example, with 1000 calibrated peaks only two calibration levels may be defined for each peak. With fewer peaks more levels may be defined in proportion to these limits (for example, 100 peaks could have 20 levels

to calibration capability. The user can group calibrations into a named group and see quantitative results for both individual group members and itself.

## Data Analysis - Standard Reporting

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A standard set of user definable report styles for sample reporting are selectable from the report specification screen. Every standard report type contains standard information groups and a series of optional information groups.

The standard groups include

- A header with the originating data file and sample name.
- A footer with the instrument name, operator name, print time and page number in 'page x of y' format.
- A sample information block that includes sample name, vial number, method and sample information, operator name and instrument name and sample information text.
- A quantification results table containing retention time, the integration or quantification table depending on the quantification scheme chosen. The table can be formatted either by retention time or by signal.

Users may select from a series of optional information groups by specifying a particular style for the analytical report. These groups include

- A front page that can include user-defined text.
- Repetition of the sample information block on every page.
- Instrument conditions.
- The analytical column for LC and LC/MSD systems.
- The run logbook.
- The chromatogram with annotation options that include selection from peak retention times, compound names, tick marks, baselines and axes. The user

may also select the annotation fonts, graphical orientation, size and whether the graphics are overlaid or separated. If the ChemStation is connected to instruments that can record instrument parameters as a signal, such as temperature, flow and pressure, the user may also select to include these graphics in the report.

- Calibration table and calibration graphics.

Reports may be output to either the screen, printer or file.

If the screen is selected as the

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select more than one format for a report.

**.TXT** – The report text is printed as a UNICODE text file.

**.EMF** – Each report graphic (signal or calibration curve) is saved in a Microsoft Windows metafile (EMF). Several .EMF files for one report are possible. The generated file format adheres to the Microsoft enhanced metafile format as defined in the Windows software development documentation. These files are compatible with the Aldus Placeable Metafile (APM) format used by a number of proprietary software packages.

**.DIF** – The tabular report data is saved in Data Interchange Format (DIF). This format is accepted by spreadsheet programs such as

Microsoft Excel. Independent from the report style selected, only the information contained in the report style Short will be saved.

**.CSV** – The report is in Comma Separated Values (CSV) format. This is a very simple format for tabular data that is accepted by many spreadsheet programs and databases. Independent from the report style selected, only the information contained in the report style "Short" will be saved. There can be several .DIF and .CSV files for a single report. For each report block, the first file, for example, REPORT00.CSV, contains the report header information. Subsequent files contain the results. If the results are sorted by retention time, only one file is required for the complete report, for example, REPORT01.CSV. If the results are sorted by signal, a separate table is required for each signal. In this case, the files are named Report01.CSV through ReportNN.CSV, where NN is the number of the signal.

**.XLS** – The report is exported to a Microsoft Excel spreadsheet in (XLS) format. The data generally requires additional processing.

**.HTML** – Results are saved in Hypertext markup language for viewing in web browsers.

The Agilent ChemStation for CE has an additional mobility report that uses the voltage signal and the electropherogram to compensate for the velocity of the compounds migrating through the detector cell.

## Data Analysis - Specialized Reporting

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Advanced reporting capabilities are also included in the 32-Bit ChemStation for users who require a more specialized set of reports. These include statistics on separation quality, reports that include trend analyses between samples and user-defined report layouts.

### System Suitability Reports

System suitability reports enable users to report system performance parameters for individual analyses. There are three options, or styles of these reports:

The *Standard Performance* style prints parameters for individual methods that include

- retention time,
- capacity factor,  $k'$ ,
- peak area,
- peak height,
- symmetry,
- true peak width at half height,
- efficiency in plates,
- resolution, and
- selectivity.

For calibrated methods the compound name and amount replace the peak area, height and selectivity columns.

The report header includes the standard header and footer, sample information block, the analytical column parameters and optionally a plot of the chromatogram.

The *Performance and Noise* style adds an evaluation of the signal noise, in up to seven user-defined evaluation ranges, to the data from the performance report style.

The noise parameters are reported as a signal-to-noise ratio for each peak or calibrated compound and a noise table for each signal. Each noise table includes noise calculated by the six times standard deviation, peak to peak and ASTM methods as well as the wander and drift.

The *Extended Performance* style adds plots of each individual peak showing graphically the peak start and stop times, half width and

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- statistical moments ( $M0$  to  $M4$ ),
- peak width at half height calculated by the true, five sigma, tangent and tailing methods, and
- plate/column and plates/meter calculated by the peak width at half height, five sigma, tangent and statistical methods.

Users may define their own noise evaluation ranges and acceptable limits for these performance criteria. Values lying outside the user-defined acceptable limits are indicated on the report.

### Sequence Summary Reports

Sequence summary reports are produced at the end of a series of automated analyses. Their range of application is from a brief summary of the samples analyzed to a

detailed graphical repeatability or trend analysis of user-selectable parameters between different samples analyzed by the same method. The reports are built up from nine optional categories of information:

- a header page that may be user defined,
- the instrument configuration including revision numbers and analytical column or capillary specifications for LC, CE and LC/MSD systems,

• a list of samples scheduled for analysis, a book printout which shows what was analyzed and the data acquisition processing steps as well as expected events, a list of the analytical results, individual sample reports, and a list of calibration samples,

- statistics on unknown samples, and
- a summary page that may be either a sample summary, one line of information per analysis, or a compound summary with a short compound summary table in addition to the sample summary.

The statistical reports may be selected as standard or extended styles. The *Standard Style* is text-based and includes the mean, standard deviation (SD), relative standard deviation (RSD) and standard error for the following parameters tabulated by compound:

- retention time,
- area,
- height,

- peak width, and
- peak symmetry.

The *Extended Style* includes graphical trend analyses based on a selection of parameters for statistical evaluation. The parameters that can be selected include

- retention time,
- area,
- height,
- amount,
- peak width at half height, by the sigma, tangent and tailing methods,
- peak symmetry,
- tailing factor,
- capacity factor,  $k'$ ,
- theoretical plates by the peak width at half height, sigma, tangent and statistic methods,
- resolution by the peak width at half height, sigma, tangent and statistic methods,
- selectivity,
- skew, and
- excess.

Technique specific parameters for liquid chromatography include:

- peak purity evaluation factors (with the diode-array spectral evaluation module only), and

- spectral library comparison factor (with the diode-array spectral evaluation module only).

The report includes a separate graphical trend analysis for each selected parameter. Sequence summary reports may be output to the printer, to file or both. The user may select to either print or suppress individual analysis reports together with the sequence summary.

#### Customized Reports

A customized reporting design view is included in the ChemStation for users who want to

The user may define headers and footers to appear on every page, time stamps for the report and page numbering in the 'page x of y' format. The information included in the report may be any ChemStation or user-defined parameter.

Once the report has been designed it may be associated with a particular method to make it the default report format for that particular type of analysis.

Customized reports may be output to the screen, a printer or a file. Reports to the screen include

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#### Smart Reports

Smart Report feature is included in ChemStation software. Once the feature is installed and the user may automatically select a parameter of interest and each time a method is run the parameters include:

Amount, Response Factor, Retention Time, and Area.

## Utilities and Compatibilities

### General

The ChemStation can import and export data files in the ANDI (Analytical Data Interchange) chromatography format of the Analytical Instrument Association (AIA), revision 1.0, copyright 1992. Data import is supported at com-

pliance level one (sample information and signal data) and data export at compliance level two (sample information, signal data and integration results).

The ChemStation includes commands and functions to support the Dynamic Data Exchange

(DDE) standard of the Microsoft Windows platform as both a DDE client and a DDE server. The command set includes commands to establish and terminate connections, transfer information in both directions and execute remote functions.

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### Data Analysis - Integration

All files (data files, methods, sequences, log files etc) created on previous ChemStation Rev. A.xx.xx systems can be loaded and used in the new 32-Bit Rev. B.01.0x ChemStation. The Rev. B.01.0x system converts Rev. A.xx.xx files to a new structure during saving. The new structure

is not compatible for use with older Rev. A.xx.xx or B.01.0x systems. The system will warn users to save files with a new name when performing the one-time conversion from Rev. A.xx.xx in the new system. To maintain backwards compatibility it is recommended to save converted files with a name different to the origi-

nal Rev. A.xx.xx file or B.01.0x.. This preserves the original Rev. A.xx.xx file which can continue to be used with ChemStation Rev. A.xx.xx or B.01.0x systems if desired.

### XML Interface

XML (eXtensible Markup Language) is a protocol for structuring data in pure text format. An XML file contains data in an embedded structural format and, being pure text, it can be edited with a simple editor such as Notepad. XML has become a flexible and portable format especially for exchanging data between different systems.

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data into the ChemStation sequence. This process can be automated using the ChemStation macro language. In addition the

XML interface allows manual or fully automated export of sample and information. The XML interface files provided with the ChemStation are allow an easy adaptation for a specific interface for a specific application or knowledge Management system. More information is available in the Agilent ChemStation XML interface users guide (G2170-90223).

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### Customization

The ChemStation can be customized using a powerful command set. These commands may be grouped to automatically execute a specific function; such a group is called a macro. Users writing macros may define their own variables, build in conditional or looping constructs, perform physical I/O including file handling and

user interaction, nest their macros and schedule and exchange data with other MS-DOS or Microsoft Windows applications.

More information on customization is available in the *Macro Programming Guide* within the Agilent ChemStation online help.

## Automation

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The ChemStation can execute multi-method sequences.

All data generated during a sequence is stored in a unique sequence container along with the actually used methods. The pattern used for naming of the sequence container can be configured to contain a combination of, for example, date, time, operator, instrument, PC or sequence name.

The sequence parameter set may be defined to use automatically named data files or sequentially numbered ones with a user-defined prefix of up to 16 characters. The user can run full analyses or reprocessing only sequences. The user can also select one of a series of unique specific shutdown commands or a user-defined macro that runs when the sequence terminates successfully or after all the analyses are completed.

The sequence table, or list of analyses to run, is built in a spreadsheet-like user interface that allows users to specify vial numbers and sample names, analysis methods, sample quantification parameters including sample amount, a multiplier and dilution factor, calibration specification, a data exchange parameter (LIMSID) and the number of repeat injections. Depending on the configured instruments and modules, additional fields will be accessible. For example if an Agilent 1200/1100 LC system includes a fraction collector the "Fract. Start" column will appear in

the sequence table. The user can configure the columns to be displayed in the sequence table as well as the individual column widths. The user can jump between individual cells in the table and copy, cut or paste individual cells or entire rows or series of rows in order to build sequences efficiently and quickly. A sequence table can easily be created or changed using the fill-down wizard function. The sequence import wizard allows the import of sequences from any kind of delimited text file.

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- Calibration samples are used to recalibrate the quantification component of the method as described below, and
- Control samples are evaluated against the limits for each component defined in the method. If the results lie outside any specified parameter range the execution of the sequence will be halted.

Calibration samples may be defined as simple, cyclic or bracketed. Simple recalibrations mean a recalibration occurs each time a calibration sample is defined in the sequence. Cyclic recalibrations occur at defined intervals during analysis of a series of

unknowns. In bracketing a series of unknown samples are analyzed between two calibration sets. The quantitative reports for the unknown samples are then calculated using a calibration table averaged between the two calibration sets.

When re-evaluating data already acquired users can specify whether reprocessing uses the original sample quantification data or new data entered in the sequence's sample table.

Sequences may be paused to run injection priority samples or another method then restarted without disrupting the automation. Samples can be added to the sequence table while the sequence is executing.

The sequence and partial sequence tables may be printed.

Stepping (even automatically) through the navigation table in Data Analysis View also allows for a fast review of samples.

Batch Review is an additional mode of data analysis that provides automation by allowing a fast and easy first-pass review of a batch of samples. The batch consists of all or a selection of runs from a sequence. You can check the calibration accuracy and the individual integrations before approving the results. All chromatogram-specific modified integration parameters can be saved for data traceability. Once data is accepted the entire batch can be reprocessed to generate reports with one keystroke.

## Good Laboratory Practice

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The 32-Bit ChemStation is developed to internationally recognized design and development standards and has a number of features specifically to help users operating in a regulated environment. These features help users validate and specify methods, verify that methods are fit for their intended use, verify system performance and operation and ensure the traceability, integrity and security of the data.

### Development Process

The Agilent Certificate of Validation shipped with the software package documents the development and steps executed as part of the development cycle. The development process is registered to ISO 9001 quality standards and is documented together with revalidation protocols in the Validation CD-ROM.

### Method Specification and Use

- Global methods — the complete instrument and data analysis specification is stored in one place. Methods include individual compound range specifications to check that quantification results are not applied outside the calibrated range.
- The method change history log allows users of a validated method to automatically record how and when a method was changed. Users may add a reason for the change to the

change history log. The change history log is automatically stored as part of the method. To prevent unauthorized access to the records it is protected by the user access scheme, described below. The change history log may be viewed and printed.

- Limits may be assigned on a compound-by-compound basis in each method for a number of chromatographic and system performance parameters, as described in the data analysis quantification section. Results exceeding these parameter

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The ChemStation may be configured for restricted access through two user access levels, an operator and manager level. The manager level may be password protected and allows access to the complete ChemStation functionality. The operator level restricts the user to key functionality and to executing defined analytical methods. The operator level is intended for use in routine laboratories and specifically prevents users from modifying and creating new methods.

### Method Robustness

Sequence summary reports (see section “Data Analysis - Specialized Reporting”) provide a means to test methods for robustness. The extended format reports for user-selected criteria are reported as trend charts and may be used to determine the realistic operation limits. These limits can then be incorporated in the method to ensure, through the analysis of control samples, that the method is operating within specifications.

### Operation

ChemStation software verification kit, that is part of the standard software, automatically performs the correct operation for the correct operation of the data evaluation parts of the system by comparing results with pre-recorded known values. The verification test allows users to define their own data files and methods to be the basis of the test.

### Data Traceability, Integrity and Security

- The run-time logbook provides a transaction log of the complete system. It also records any unusual events (such as errors or parameter changes made during a run), as well as the instrument conditions before and after each analysis. A copy of the relevant logbook extract is saved with each data file.

- 
- The actual instrument conditions, such as pressure, flow, and temperature, that occurred during each analysis are also recorded if the configured instrument supports this capability. This data can be subsequently displayed graphically with the chromatogram to show the actual instrument conditions during that particular analysis. These graphics may be included on each report.
  - Methods saved record the actual time of the analysis, the complete run time, the reported date, the method name, the completion time, and the actual steps.
  - All reports have and traceable page numbering ('page x of y' style). The user may select the level of detail in each report ranging from simple summary reports to complete system details (see Reporting section).
  - GLP save register files, specified as part of the method configuration, save all the original data including sample information, data analysis method, chromatographic signals, instrument conditions, integration and quantification results, report data and the run logbook in one checksum protected binary file. This is an uneditable binary format that ensures the integrity of the results. The file includes a revisioning scheme that indicates if data has been reprocessed.
  - Control sample types may be defined in the sequence table and used to automatically check the instrument performance against quality control sample results when the instru-

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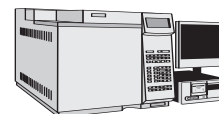
## Instrument Control

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The instrument control capabilities of the Agilent ChemStation may be expanded through the purchase of additional instrument

modules to allow multiple instrument, mixed technique configurations. The instrument control capabilities are documented in the

following sections, each relating to a specific technique.



## Agilent ChemStation for GC

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### Instrument Control and Data Acquisition with the Agilent ChemStation for GC (G2070BA) and the Additional GC Instrument Module (G2071BA)

The Agilent ChemStation combines instrument control, data acquisition, and data analysis software for the Agilent 6890 Series II, and 4890D Series chromatographs and the 35900E A/D converter.

The Agilent ChemStation is interfaced to the GC via LAN, RS-232, or GPIB and collects full range digital data from detectors. Depending on the detector type, data can be acquired at rates up to 20 Hz from the Agilent 5890 and Agilent 4890D Series and up to 200 Hz from the Agilent 6890 and Agilent 6850 Series.

When interfaced to an Agilent gas chromatograph, the Agilent ChemStation can control GC parameters for heated zones, oven temperatures, detectors, inlets, cryogenic cooling, signals, electronic pressure and flow control, and cool on-column temperature programming.

In addition to GC control the following features are noted:

- Graphical user interface for easy access to all method areas for all Agilent GCs
- Table-driven system scheduler

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Agilent 6890 and Agilent 6850 Series only) will verify and alert the operator of potential problems if a method was created on a different GC system or if the configuration has changed.

- Capillary columns can be calibrated from the ChemStation

The Agilent ChemStation can display graphically the oven temperature, inlet temperature, inlet pressure, auxiliary channel pressure and column flow programs. The Agilent ChemStation also can control, through a timetable, a maximum of eight valves or relays.

### Sampling

The Agilent 7673C and Agilent 7683 Series automatic samplers allow for complete automation of introduction in single or dual rear or dual-injector configurations.

Injector configurations (6890 Series, 5890 II, and 4890D Series GCs) allow individual or simultaneous injections. Each automatic sampler allows a 3-vial or 100-vial turret, or 100-vial access if a sample tray is fitted. (6890 and 5890 Series only). The 6850 GC also supports the G2880A 22/27 positions tray. The Agilent ChemStation allows random sample access and priority sample injection.

The following autosampler parameters may be controlled:

- number of syringe pumps
- number of syringe washes
- the injection volume
- the bottle number for each injection
- a viscosity delay
- on-column injection setup
- syringe size
- depth of needle penetration

- multiple injections per run in cooperation with PTV for large volume injection
- For the Agilent 7683 Series, plunger speed may be controlled from a maximum of 100 µl/sec to a minimum of 5 µl/sec when using a 10 µl syringe.
- For the Agilent 7683B, larger turret for 2x increase in solvent and waste capacity (6890, 6850 only).
- For the Agilent 7683B, solvent saver made for 4x increase in solvent usage (6890, 6850 only).
- For large volume injections a 100-µl syringe can be used with the Agilent 7683 Series.

The Agilent ChemStation provides the user to optionally display the Sampling Diagram window containing a graphical display of one hundred vial tray, indicating which samples have already been analyzed and which sample is currently being analyzed and which samples will be analyzed next.

The G1926A bar code reader attachment is supported in the 100-vial tray configuration of the autosampler. The bar code reader can be used to help build automation sequences and verify that the identity of the injected sample matches the name in the sequence table at injection time.

The new G2615A bar code reader is used with the 7683 automatic liquid sampler tray.

The Agilent ChemStation can acquire a third and fourth signal from external detectors in a single run by adding the 35900E A/D converter.

### Agilent GC ChemStation Companion

The Agilent ChemStation Companion provides the user with a simple single-screen user interface for GC routine analysis. In the Companion View, the user is limited to selecting pre-programmed samples, methods, vial numbers, and run control. Users cannot modify or create any methods or run any methods or samples not assigned to them by their lab manager. The Agilent ChemStation Companion is installed automatically during the GC software installation.

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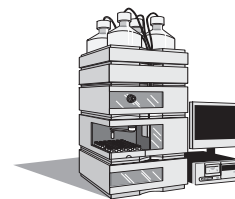
Agilent's ChemStation software uses retention times to match analyte retention times between and among Agilent GC systems. RTL is essentially based on void-time matching through an empirically determined pressure-retention time calibration curve. RTL calibration curves are specific to the analyte chosen (pick one analyte in your standard, the best choice is a peak well separated from other peaks and in the middle portion of the chromatogram), type of column used (stationary phase type, phase ratio, and column dimensions), carrier gas type, and oven temperature program used in the method. Once the calibration has been done for an initial

("original") method, the method and its associated RTL calibration can be transferred to another instrument with the same column type and carrier gas type. RTL software in Agilent ChemStations assists with the process of determining and using RTL calibrations.

To lock a new system to the original system, carrier gas head pressure is adjusted using the RTL calibration curve. The retention time of a target compound (same one used to generate the RTL calibration) can be locked onto the desired retention time value. All subsequent retention times will match those of the

original system. The RTL software also provides the user the ability to search retention times. Searching unknowns is primarily on retention times but also include element analysis (such as one might get from mass selective detectors) to narrow search results further. Users can create, edit, import and export RTL libraries.

The RTL Pesticide Library, product number G2081AA, includes the retention times for pesticides and suspected endocrine disrupters. To use this library, the RTL software product G2080BA must be installed. Peak identification is performed by comparing the retention time of the unknown peak with that of a standard included in the library table.



## Agilent ChemStation for LC Systems

### Instrument Control and Data Acquisition with the Agilent ChemStation for LC Systems (G2170BA) and the Additional LC Instrument Module (G2171BA).

The Agilent ChemStation for LC and additional LC instrument module controls and acquires data from the Agilent 1200/1100 Series modules and systems for LC, the HP 1090 Series liquid chromatography systems with either the filter photometric detector (FPD) or built-in diode-array detector (DAD), the stand-alone diode-array detector (DAD), the HP 1046A fluorescence detector (FLD), the HP 1049A chemical detector (ECD) and Agilent 35900E dual channels. All the sampling and detector options of Agilent 1200/1100 Series and systems for LC, and HP 1090 Series liquid chromatographs can be controlled.

### Sampling Systems

The injection systems may be manual or automated with an autosampler or well-plate autosampler. All automatic injectors may be programmed for different injection volumes, the speed of injection and the injector wash procedure. The user may also specify a complete injector program for sample dilution, standard addition or sample derivatization. The commands available for the injector program include draw, eject, mix, wait, inject, sampler valve and column switch control. These can be defined in conjunction with the sample, a vial/well-plate

offset from the sample, a numbered vial/well, waste and air.

The Agilent bar code reader (G2256A) is available for selected autosampler configurations. It can be used to help build automation sequences and verify the identity of the injected sample matches the name in the sequence table at injection time. In LC configurations it can also be used to mix liquid samples as a step in an injection program.

The following Agilent 1200/1100

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- (G1367B)
- Well-plate autosampler (G1367A)
- Thermostatted well-plate autosampler (G1368A)
- Micro well-plate autosampler (G1377A with illumination)
- Thermostatted micro well-plate sampler (G1378A)
- Thermostatted micro autosampler (G1387A)
- Preparative autosampler (G2260A with illumination)
- Thermostatted preparative sampler (G2261A)
- Agilent sample capacity extension (G2257A) for the 1100 Series well-plate sampler G1367A and micro well-plate sampler G1377A
- Agilent dual loop autosampler (G2258A with illumination)

- Agilent thermostat option (G1330A /B)
- Agilent fraction collectors (G1364A /B/ C/D)
- Agilent 1200/1100 Series barcode reader (G2256A) for the sample capacity extension (G2257A)

### Solvent Delivery Systems

All the solvent delivery systems have a set of initial parameters, including pressure limits, initial flow and composition, that are complemented by a time-table for programming changes in flow, composition and pressure limits. Parameters can be viewed dynamically. Users can define a time for column equilibration.

The following Agilent 1200/1100 solvent delivery systems are supplied:

- Isocratic pump (G1310A)
- Binary pump (G1312A)
- Binary pump SL (G1312B)
- Quaternary pump (G1354A / G1311A)
- Preparative pump (G1361A / G1391A with gradient extension)
- Capillary pump (G1376A pump only / G1382A with degasser)
- Agilent 1200/1100 nanoflow pump (G2226A pump only, G2225A with degasser)

### Column Compartments

The Agilent 1200 Series thermostatted column compartment SL (G1316B) can be set between 10 °C and 100 °C and provides post column cooling capability.

The Agilent 1100 Series thermostatted column compartment can be set between 10 °C below ambient and 80 °C. The temperature is programmable during the run through a timetable. The HP 1090 column oven temperature can be set to a constant temperature (20 °C above ambient to 100 °C without external cooling). Column switching valves are programmable from the software.

## Valves

The Agilent ChemStation supports external valves as well as thermostatted valves built into the column compartment.

The following external valves are supported:

- Agilent 1200/1100 Series 2-position/6-port valve (G1156A)
- Agilent 1200/1100 Series 2-position/10-port valve (G1157A)
- Agilent 1200 Series 2-position/6-port valve SL (G1158B)
- Agilent 1200/1100 Series 2-position/6-port (standard) valve (G1158A)
- Agilent 1200/1100 Series 6-position selection valve (G1159A)
- Agilent 1200/1100 Series 12-position/13-port selection valve (G1160A)
- Agilent 1200/1100 Series 2-position/6-port (micro) valve (G1162A)
- Agilent 1100 Series 2-position/10-port (micro) valve (G1163A)

The following thermostatted valves built into the column compartment are supported:

- 2-position/6-port valve option (G1316B# 055) up to 600bar
- 2-position/6-port micro valve option (G1316B # 056) up to 600bar
- 2-position/10-port valve option (G1316B # 057) up to 600bar
- 2-position/6-port valve option (G1316A# 055)
- 2-position/6-port micro valve option (G1316A # 056)
- 2-position/10-port valve option (G1316A # 057)

The maximum number of external valves connected to one Agilent

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The Agilent 1200 Series diode-array detector (DAD-SL), G1315C, and the Agilent 1200 Series multi-wavelength detector (MWD-SL), G1365C, support 80 Hz full spectral data acquisition. The G1315C and G1365C support up to 80 Hz data acquisition of up to 8 signals, additional instrument curves and offer data buffering on a built-in Compact Flash Card to provide 'data never lost' insurance. The cells and UV lamp utilize RFID tags to capture and store lamp and cell information. The improved Temperature Management System provides ambient rejection and stable cell temperature.

The ChemStation software can simultaneously acquire five chromatographic and reference signals each with an independent bandwidth from the *Agilent 1100 Series diode-array detector (G1315A or G1315B)*.

The system can simultaneously acquire up to a total of eight chromatographic and reference signals from the *HP 1090* with an independent bandwidth.

The detectors have a graphical test for signal intensity and wavelength calibration. All DADs may have the parameters changed during a time-based program. The HP 1090 can program wavelength spectral acquisition mode and parameters in the time table.

The parameters that may be programmed for the DADs include signal intensity, wavelengths and reference wavelengths, spectral acquisition mode, signal sampling rate and autobalance.

The *HP 1090 filter photometric detector (FPD)* may be programmed with parameters to set the lamp current, response time and the filter. The filter may be changed during an analysis through events in the detector's time table. The ChemStation includes a diagnosis screen for testing the reference and sample photo diode light paths in the detector. The FPD is interfaced to the ChemStation through the digital GP-IB interface for control and through a dual channel A/D interface for the data acquisition.

The excitation and emission wavelengths of the *HP 1046A*

*Fluorescence Detector (FLD)* can be set from 190 to 800nm, in steps of 1nm. Gain, response time, gate, delay and lamp frequency may also be set. Gain and changes in the emission and excitation wavelength may be time-programmed. The excitation and emission wavelengths may be optimized by analyzing scans. The range and speed may be specified for each scan during the optimization process. The scans taken during an analysis are stored in a ChemStation spectral file format that allows them to be displayed and compared to a spectral library.

The *HP 1049A Electrode Detector (ECD)* may be used for amperometry, pre-treatment, sweep, pulse and differential mode. The voltage potential limits may be defined between -2.0V and +2.0V in steps of 0.001V. A voltage potential increment between analysis may be defined from -2.0V and +2.0V in steps of 0.001V and the number of repeat analyses at a given increment may be set. Drift limits for the detector not ready condition may be specified from 0.1 nA to 500 nA in steps of 0.1 nA. The user may also specify auto-zero control, based on the prepare or stop signal or a user defined drift value, full scale detector output at 0.05 mA or 500 mA, the signal polarity and the temperature of the solvent thermostat (20 to 60°C).

The *Agilent 1200/1100 Series variable wavelength detector (VWD)* may be programmed with a single detection wavelength. Data acquisition rates may be programmed for peak widths from <0.12 up to 8.00 seconds. The VWD can be programmed with a timetable to change the wavelength and perform wavelength scans during the course of an analysis.

The *Agilent 1200 Series multiple wavelength detector (MWD-SL)*, (G1365C) can simultaneously acquire

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temperature.

The *Agilent 1200/1100 Series multiple wavelength detector (MWD)* (G1365A or G1365B) can simultaneously acquire up to five chromatographic signals each with independent reference wavelengths and bandwidths. The signal acquisition rate may be set for peak widths between 0.1 and 16 seconds. During the course of an analysis the MWD can be programmed with a timetable to change wavelengths, bandwidths and peak-widths for all five wavelengths.

The optical unit temperature of the *Agilent 1200/1100 Series refractive index detector (RID)* can be set between 20 and 55°C. The signal acquisition rate may be adjusted for peak widths from <0.12 up to 8 seconds. During the course of an analysis the RID can be programmed with a timetable to change Polarity and Peakwidth of the acquired chromatographic signal. For diagnostic and troubleshooting purposes, it is possible to store Diode Signal 1, Diode Signal 2, Optical Unit Temperature, Polarity and the Balance Signal in the ChemStation file format to the chromatographic

The *Agilent 1100 Series fluorescence detector (FLD)* may be programmed for single wavelength or simultaneous multiple wavelength excitation and spectra acquisition. Four signals at different excitation wavelengths and different emission wavelengths may be obtained. Within a timetable initial excitation or emission wavelengths, response time, PMT Gain and baseline behaviour as well as spectral parameters may be changed. Excitation or emission spectra can be watched online and stored and analyzed as described for DAD spectra. For a single compound trapped in the flow cell, complete information on excitation and emission spectra is available in a single task with the fluorescence scan and can be watched as an iso-plot or as 3D-graphics.

The *Agilent 35900E dual channel interface* allow the system to acquire data from detectors that are not interfaced for data acquisition through GP-IB or LAN, such as the FPD, the HP 1047A refractive index detector or a third party detector. One or two analog signals per instrument may be configured; if only one is used the other is available for use with another instrument. Data rates up to 100 Hz per signal may be defined. The user may also define the units for acquisition and their relation to the voltage signal (units/

The Agilent 35900E interface offer external event control through digital TTL (transistor logic) signals, each which are given specific state (high and low) names, that time-programmed before, during and after an analysis. The Agilent 35900E can be configured for up to eight signals for each independent channel.

### **Fraction Collectors**

All different versions of the Agilent 1200/1100 Series fraction collectors (G1364A, G1364B, G1364C, G1364D) can be fully controlled from Agilent ChemStation. Fraction data can be reviewed in the fraction task of the data analysis screen. The maximum number of fraction collectors connected to one Agilent 1100 Series Purification system is limited to 3 (with the possibility for one additional recovery fraction collector).

Depending on the system configuration up to two Purification systems can be controlled from single ChemStation system (without purification related software add on). Optional add-on software, e.g. High/Throughput Purification software (G2262AA, G2263AA, G2265AA) or Easy Access (G2725AA) provides advanced functionalities.

### **Agilent 1200/1100 Series Instrument Verification**

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To perform instrument verification it is first necessary to purchase the relevant service from Agilent Technologies. The required method and sequence files will be installed at the time of service delivery by an authorised Agilent service provider. Please contact your local Agilent Technologies representative for more details.

### **Agilent 1200/1100 Series Diagnostics**

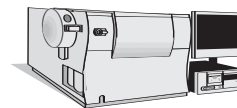
The Agilent 1200/1100 Series of systems and modules for LC have an additional ChemStation diagnosis view.

The diagnosis view is designed to help users identify instrument malfunctions starting from a particular symptom. A failure of a particular instrument verification test will automatically identify the appropriate symptom for the user or the user may select the symptom interactively.

One or more possible causes is listed for each symptom. Each possible cause is associated with a series of diagnostic measurements, limits, and a series of tests. Users observe the symptoms and carry out the tests to confirm or disprove the possible cause of the malfunction.

When the cause of the malfunction may be identified, the cause of the malfunction may be confirmed using the repair procedure on the Agilent

1200/1100 Series Maintenance and Repair CD-ROM. The repair procedures include parts and materials breakdowns and clear animated step-by-step graphics or video with a sound track for each repair procedure. The procedures are called directly from the Agilent ChemStation diagnostics view.



## Agilent ChemStation for LC/MSD Systems

### Instrument Control, Data Acquisition, and Data Evaluation with the Agilent ChemStation for LC/MSD Systems (G2710BA) and the LC/MSD ChemStation Add-on Module (G2715BA)

The Agilent ChemStation for LC/MSD systems (G2710BA) and the LC/MSD ChemStation Add-on module (G2715BA) provide control, data acquisition, and data evaluation capabilities for Agilent 1200/1100 Series LC/MSD systems. The G2710BA and G2715BA LC/MSD software include the G2170BA LC ChemStation G2180AA diode-array detector (DAD) spectral evaluation Add-on module. Together, these software components provide integrated control with a graphical user interface for the Agilent 1200/1100 Series LC/MSD modules and systems, including the Agilent 1200 Series DAD as well as the Agilent 1200 Series LC/MSD. In addition to the Agilent 1200 Series family of modules and systems, the HP 1090 Series II liquid chromatography system, as well as the Agilent 35900E A/D interface can be controlled by G2710BA as part of LC/MSD systems. The Agilent ChemStation for LC/MSD system supports a single Agilent 1200/1100 Series LC/MSD system.

### LC/MSD System Control

The software provides digital control of the LC/MSD API ion source and ion optics, dynamic ramping of ion optics element voltages, and control for spraying and drying gases. Method-specific LC/MSD parameters include spectral acquisition mode (scan/SIM), signal sampling rate, LC/MSD tune file, ionization mode (APCI, APPI or API-ES mode) and polarity (positive or negative ion detection).

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Temperature, nebulizer voltage, drying gas temperature, and EMV gain can be acquired and saved with a data file. These instrument parameters can be displayed and plotted as a record of the exact values associated with the acquired data.

In addition to the standard ChemStation automation capabilities for single run methods and multiple method sequences, an FIA (Flow Injection Analysis) Series automation mode is available through software selection. In this mode, which requires the Agilent 1200/1100 Series LC autosampler,

the Agilent 1200/1100 Series LC/MSD system can be programmed to make multiple injections from a single or multiple sample vials, storing all data in a single datafile. Up to two LC/MSD method parameters can be programmatically varied with each injection.

The system includes the ability to do fast scanning of up to 5250 amu/sec and includes autotune for fast scanning. Also included is the Agilent Analog Accessory which provides SIM signals directly to a LIMS system.

### Tuning

The Agilent ChemStation for LC/MSD systems includes a tune view in which users can select the Agilent 1200/1100 Series LC/MSD may select to either automatically, or manually tune the instrument. The Agilent 1200/1100 Series LC/MSD integrated calibrant delivery system is software-controlled, and together with the software autotune provides fully automated tuning of the Agilent 1200/1100 Series LC/MSD for API-electrospray (API-ES), atmospheric pressure chemical ionization (APCI) and atmospheric pressure photo ionization (APPI) modes of operation. An extensive set of manual tune capabilities is also provided for users who wish to manually tune the Agilent 1200/1100 Series LC/MSD.

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### Agilent 1200/ 1100 Series LC/MSD Instrument Verification

Computer-aided operational qualification (OQ/PV) tests and procedures can be used to verify that system performance is acceptable on an ongoing basis. Early maintenance feedback (EMF) tracks the status of system maintenance items and provides notification when a preventive maintenance procedure is due. On-line diagnostics enable system troubleshooting using integrated tests. System logbooks provide date- and time-stamped records of runs, errors, and maintenance events.

To perform instrument verification it is first necessary to purchase the relevant service from Agilent Technologies. The required method and sequence files are installed at the time of system delivery by an authorized service provider. Please contact your local Agilent Technologies representative for more details.

### Diagnostics/Early Maintenance Feedback

The Agilent 1200/1100 Series LC/MSD software extends the diagnosis view of the existing LC ChemStation to include tests for the Agilent 1200/1100 Series LC/MSD. The diagnosis view is designed to help users identify instrument malfunctions starting from a particular symptom. Maintenance and repair procedures for the Agilent 1200/1100

Series LC/MSD can be called directly within the diagnosis view from the Agilent 1200/1100 Series LC/MSD Maintenance and Repair CD-ROM. The procedures include parts and materials breakdowns and clear animated step-by-step graphics and multimedia clips for each repair procedure.

Early Maintenance Feedback (EMF) automatically notifies the user when maintenance is required for key system components such as rough pumps, calibrant delivery system, spray chamber, and electron multiplier.

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Station includes capabilities for evaluation of mass spectral data acquired from the Agilent 1100 Series LC/MSD module.

Both UV-visible and LC/MSD data can be viewed, compared, and printed. Chromatograms from the separate detectors may be simultaneously displayed, aligned, and resized to correlate peaks from one chromatogram to the other. Mass spectra and UV-visible spectra can be simultaneously reviewed using a common spectral toolset. Reports can include either UV-visible or mass spectral data, or both.

### Interactive Data Processing

The data from the mass selective detector may be displayed in a number of ways. The total ion chromatogram (TIC) is the summation of all mass signals ( $m/z$  values) over the entire acquired data range. An extracted ion chromatogram (EIC) displays the signals of individual ions ( $m/z$  values) or a range of  $m/z$  values.

The mass selective detector signals (TIC and/or EICs) may be displayed along with those from UV-visible detectors. The software provides peak alignment for chromatograms from different detectors connected in series. Full, interactive mass and UV-visible manipulation are available including selection of spectra by: full spectrum, apex spectrum, or the spectrum over a graphically defined retention time range

- range of spectra, and
- all spectra over a peak.

The user may also select how the spectra are processed when they are displayed. The available options include:

- background subtracted spectra,
- limiting the  $m/z$  range,
- smoothing,
- normalization, and
- continuous curves or histogram mode.

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## Quantification

All of the standard ChemStation quantification capabilities are available for use with mass spectral data. TIC or EIC signals can be used for quantification. For target compound analysis, retention time windows, quantification ion signals, and qualifier ion signals/ratios can be defined on a per-compound basis.

## Peak Purity

The LC/MSD ChemStation includes all the UV-visible peak purity data evaluation capabilities of the Agilent diode array detector (DAD) spectral evaluation. Capability for peak purity evaluation using LC/MSD spectral data is also included. Peak purity may be determined passively or actively on either a per-peak basis, for all the peaks in a data file, or at the end of an analysis using the method.

The user can select to interactively evaluate peak purity for data sets that include both DAD spectral data and LC/MSD spectral data in either a single or dual mode. In single mode, the software configures the purity user interface for evaluation of data from either one of the two data types at a time. The user can toggle between the data types if desired. The dual mode user interface permits simultaneous evaluation of spectral purity using both DAD and LC/MSD data.

In interactive operation, the LC/MSD peak purity function examines the most significant ions across a user-selected chromatographic peak to determine if more than one compound is present. The software automatically overlays extracted ion chromatograms for the selected peak, with each extracted ion chromatogram displayed in a separate color. A table of the number of components located and the two most significant ions used to resolve each component is displayed. The next/previous peak or the next/previous impure peak can be

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viewable spectral data, the LC/MSD ChemStation also provides equivalent capabilities for mass spectral data.

The MS iso-abundance plot displays acquired mass spectra as a color-contoured map of  $m/z$  against retention time together with areas for display of  $m/z$  signals and mass spectra defined by the position of cross-hairs on the iso-abundance plot. In the iso-abundance plot, a color scale is used to represent signal intensity. Users can define the contour color schemes and retention time and  $m/z$  ranges for the display.

Acquired mass spectra can also be displayed as a three dimensional plot of  $m/z$  against retention time and abundance. The display can be graphically adjusted by the user in the time,  $m/z$ , and intensity domains. The resolution of the plot is selectable, and the orientation of the plot can be adjusted graphically. The plot may be printed, and the color scheme adjusted.

## Agilent 1200 Chip Cube Interface (G4240A)

The Agilent 1200 Chip Cube interface is designed for LC systems using an Agilent Ion Trap MSD as detector and Bruker Software for data analysis. The ChemStation provides software support for this interface.



## Agilent ChemStation for A/D

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### **Acquisition with the Agilent ChemStation for A/D (G2072BA) and the Additional A/D Instrument Module (G2073BA)**

The A/D ChemStation and additional A/D interface acquisition module controls and acquires data from Agilent 35900E dual channel interface. These interfaces allow the ChemStation to communicate with instruments capable of being interfaced to the data acquisition through a serial system or LAN. One channel per instrument is configured; if only one channel is available for another instrument, the data is acquired at up to 10

The user may also define the units for acquisition and their relationship to the voltage signal (units/volt). The Agilent 35900E interfaces offer external event control through digital TTL (transistor-transistor logic) signals, each of which are given specific state (high and low) names, that may be time-programmed before, during and after an analysis. The

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## Additional Data Evaluation Modules

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The data processing capability of the ChemStation may also be expanded through the purchase of additional data processing modules for specific applications:

- LC diode-array detector (DAD) spectral evaluation module (G2180BA)
- Agilent ChemStore sample organization and results database module (G2181BA)

### LC Diode-Array Detector (DAD) Spectral Evaluation Module (G2180BA)

UV-visible spectra, acquired with a diode-array detector, may be graphically selected from a chromatogram signal for visual inspection and comparison or used for peak purity determinations, wavelength optimization, and component identification through spectral libraries. The spectral library functionality can be extended to automatic identification of components in up to four user-defined spectral libraries based on peak or target compound identification.

#### Interactive Spectral Processing

Users may graphically select spectra from a chromatographic signal for visual inspection and printing. The spectra are displayed in a separate spectral window and may be overlaid for comparisons. The user can select spectra in the following modes:

- individual spectrum,
- peak apex spectrum,

- average spectrum over a graphically defined retention time range,
- range of spectra, and
- all spectra over a peak

The user may also select how the spectra are processed when they are extracted. The available options include:

- setting the subtracted reference spectrum or spectra,
- limiting the extracted wavelength range,
- customizing the spectral and

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interactively on a peak by peak basis, for all the peaks from a certain data file, or automatically at the end of each analysis as part of the method. Users may optimize peak purity processing for accuracy or performance by setting preferences relating to:

- the number of spectra used over a peak,
- the wavelength range used for the purity determination,
- the reference spectra,
- the purity threshold,
- spectral processing including logarithmic, smoothing and splining factors and derivative order.

The purity components are calculated and displayed. These include the spectra, the spectral differences, the signals, a signals-based ratiogram, similarity and threshold curves.

Similarity curves give the most detailed information about a peak's purity. User selected or average spectra are compared with all the other spectra acquired during the peak's elution and the resulting spectral comparison factors are plotted as the similarity curve. For a perfectly pure peak

the similarity curve will be a straight line corresponding to a theoretically pure compound. Impurities will cause a deviation from the ideal line. The similarity curves are plotted with reference to a theoretically pure line and a user-defined purity threshold. The similarity curve gives the best estimate of any impurities that are present in the peak as it eluted.

The deviation of the similarity curve from the ideal theoretically pure value is influenced by both compound impurities and spectral noise. The user-defined purity threshold may be replaced by a system calculated threshold curve based on the signal-to-noise ratio of the peak in question. The noise sample may be user selected and, if truly representative of the spectral noise when the peak eluted, compensates for any deviation of the similarity curve, from the theoretically pure value, attributable to spectral noise.

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## Wavelength Optimization using the Iso-absorbance Plot

UV-visible spectra, acquired continuously during an analysis, can be used to determine the optimum signal wavelengths and bandwidths for routine detection by a signal-based method. The iso-absorbance plot displays the acquired spectra as a color-contoured map of wavelength against retention time together with areas for the display of both signals and spectra defined by the position of the cross-hairs on the iso-absorbance plot.

The iso-absorbance map can be used in four modes:

- Quick view mode allows users to view and compare signals and signals by moving the cross-hair over the area of interest on the contour map. Spectra are continuously extracted and updated in the display window. The extracted spectra and signals may be frozen in the display areas for comparison purposes.
- Zoom mode allows users to zoom into areas of interest on the iso-absorbance map.
- Signals mode allows users to extract a particular signal, with a graphically determined bandwidth, into the chromatographic window for routine data processing such as integration and quantification.
- Spectral mode allows users to extract spectra into the spectral window for further processing.

The iso-absorbance plot is typically used during method development to explore the sample's response at different UV-visible wavelengths in order to determine the optimal detection wavelengths and bandwidths through experimentation with the integration and quantification processes.

Users can define the contour color schemes and retention time and wavelength ranges for display.

## Three Dimensional Plot

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Rotation of the display is not restricted in any dimension.

- The plot may be printed.
- The color scheme used in the plot may be selected from a number of choices.

## Spectral Libraries

Spectral libraries allow users to positively identify compounds by comparing the spectra of peaks in the sample to libraries of spectra derived from analytical standards.

The ChemStation allows users to use libraries both interactively and automatically. The ChemStation

can manage an unlimited number of spectral libraries each with up to as many entries as there is available system memory (typically hundreds of entries). Libraries may be loaded and searched by selecting individual spectra from a chromatogram and searching the library for the best matches. The library search may be constrained by specifying a search template that allows the user to define a retention time window and include the informational data associated with each library entry. For example, the applicable retention time can be constrained to  $\pm$  the library retention time. Library entry names must start with the letter 'B'. The search results may be displayed on the screen and printed.

Users may build their own libraries by analyzing known substances under defined analytical conditions, creating a new library and entering the individual spectra and the information fields to describe the entry into the library. Library entries may be added, deleted, edited, viewed or printed. Details of each spectrum in a library including absorbance and wavelength data may be examined.

## Automated Spectral Library Search Reports

Automated spectral library search reports allow users to automatically identify and quantify unknown samples based on the positive identification from up to

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four separate spectral libraries. Search criteria may be specified for each library separately through a library search template that allows users to constrain the search both in the retention time and library entry identification parameters.

One of three search modes may be selected :

- Standard search mode identifies each integrated peak in the chromatogram from the library.
- Target analysis from the calibration table limits the library search to those library entries

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- Target analysis uses the library entries to identify peaks in the chromatogram that are within the RT window specified for the particular library entry. This mode differs from the standard search mode in that it excludes peaks whose retention times are not covered by library entry time windows.

Consequently it is typically faster than the Standard search, especially if there are many more peaks in the sample than there are entries in the library. After positive identification, quantification proceeds according to the data in the calibration table.

The calculation of the peak purity factor may be included as part of the library search.

Report styles can be selected to produce simple library search reports or a combination of library search and standard performance reports described above.

### **Spectral Data Import and Export**

The ChemStation spectral module can import spectra stored in Agilent's .WAV format files, from the HP 8452 and

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Station registers files or through the Windows clipboard.

## High Throughput Purification Software Module (Purify)

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The High Throughput/Purification software module (G2262AA) is designed for the needs of preparative HPLC. It offers utmost flexibility for purification of large numbers of samples. For efficient data review the graphical user interface provides an easy way for sample and fraction tracking. Sophisticated import and export functionality allow integration of the system purification workflow.

In addition, the MS-based fraction collection add on software package G2263AA allows fraction triggering based on up to 16 masses. And/Or fraction logic on UV and MS or other signal offers highest flexibility for complex purification tasks.

*Note: This module requires ChemStation B.2.01 SR1*

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## Agilent Chem

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The Agilent Chem database client software G2201AA may be added to any Agilent ChemStation configuration. The specifications for this product may be found in the dedicated “Agilent ChemStation Plus Specifications” document.

*Note: This module requires ChemStation B.2.01 SR1*

## Agilent Chemstation Plus Security Pack

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The ChemStation Plus Security Pack (G2183AA) is a module of the Agilent Plus Series designed to support the requirements of 21 CFR Part 11. In the Agilent ChemStation the ChemStation Plus Security Pack modifies data analysis and provides advanced data management with regard to

supporting the requirements for electronic records and electronic signature. The specifications for this product can be found in the "Agilent ChemStation Plus Specifications".

*Note: This module requires ChemStation B.2.01 SR1*

### Network

The software is thoroughly tested for standard network configurations of the Windows operating system. The software will run on a network as other networked computer applications, and adhering to the recommended programming practices of the Microsoft Windows operating environments.

These products enable the ChemStation to share physical devices such as plotters and printers with other laboratory computers as well as sharing information such as data files and methods.

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techniques and individual users while the centralized software installation relieves the burden of managing many copies of the same Agilent ChemStation installation in one work environment.

## Documentation

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The documentation set has specific components designed for:

- installing the Agilent ChemStation software,
- using the Agilent ChemStation software,
- understanding the principles of how the software works, and
- customizing the Agilent ChemStation.
- interfacing the Agilent ChemStation with LIMS
- upgrading from previous versions of ChemStation

### Installing and Learning

Each Agilent ChemStation software product comes with an installation manual that includes details of the key steps in PC hardware and software requirements, instrument interface installation, Agilent ChemStation installation and installation qualification. The installation manual is specific to the purchased configuration and includes troubleshooting, system records and system maintenance advice.

Each Agilent ChemStation includes a task-based tutorial that is built into the help. This tutorial is the primary learning aid and is designed to let users learn what they want at their own pace. Each analytical task is divided into a number of clear, guided steps each of which the users may see executed automatically by the software and then practice themselves.

### Using

Two additional categories of on-line information are designed for the routine user.

The ChemStation includes comprehensive, Windows-style, context sensitive and indexed on-line help. This system gives detailed explanations of every screen and the meaning of the parameters on that screen. The detailed explanation

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check lists to help less frequent users to deal with error conditions and set up the system correctly. These checklists are directly linked to the detailed on-line help information.

### Understanding

The *Understanding Your ChemStation* manual documents the principals of the software operation and the algorithms used in the data manipulations.

### Customization

Sophisticated users who wish to customize the operation of the

ChemStation, or who want to build in additional features, may do so by writing macros using the command set.

The Commands Help file, accessed directly from the ChemStation's Help menu or the Show command dialog box, is the programmer's function reference. It includes syntax and parameter explanations with example macros illustrating the use of commands. By virtue of the online help, the users can modify examples and command macros into their own files.

The ChemStation Plus Connectivity Guide (G2170-0000) includes installation and reference information for implementing an XML interface between the Agilent ChemStation and a LIMS (Laboratory Information Management System). The guide contains examples of the XML files and the schemas used to generate them. XML (eXtensible Markup Language) is a protocol for structuring data in pure text format. XML is a highly flexible and portable format for exchanging data between different systems.

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**[www.agilent.com/chem/cds](http://www.agilent.com/chem/cds)**

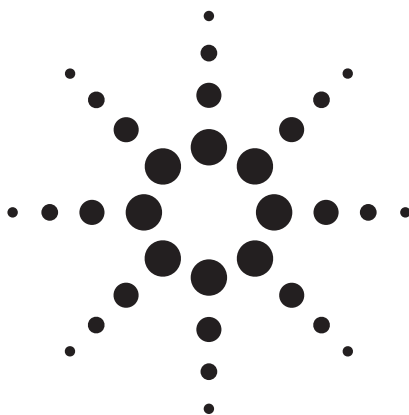
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## **Agilent ChemStation Plus Specifications**



# Agilent ChemStation Plus

July 2004

## Specifications

### General Description

This document provides information for Agilent ChemStation Plus, Agilent ChemStation Plus Method Validation Pack, Agilent ChemAccess C/S, and Agilent ChemStore C/S. With the Agilent ChemStation Plus family you need to purchase only the features you require. This can be the fully featured software package for the most advanced capabilities, or you can exclude features that you may not want now, and add them later as your needs change.

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Specifications (Agilent publication number 5988-9925EN).

**Agilent ChemStore C/S**—data organizing and storage module that provides a scalable in-process chromatographic data organization system for Agilent ChemStations (pages 2–20).

**Agilent ChemAccess C/S**—remote access module that provides a laboratory-wide remote status and control client/server data system for networked Agilent ChemStations (pages 21–23).

### **Agilent ChemStation Plus**

**Method Validation Pack**—designed to support the requirements of 21 CFR Part 312. It uses a relational database based on the ChemStore C/S for secure result data storage, data review and electronically signing off runs (pages 39–67).

**Agilent ChemStation Plus Method Validation Pack**—advanced statistics module to calculate the quality of analytical results including configuration, design and execution of method development and method validation experiments. It provides an automated printout of a complete method validation report as requested by ICH and Pharmacopoeia guidelines. All validation data are stored with versions in a built-in relational database for full data security and data integrity and to support FDA's 21 CFR Part 11 (pages 39–67).



**Agilent Technologies**

# 1. Agilent ChemStore C/S

## What's New?

With the latest revision users can benefit of new functionality in many areas as listed below.

## Workflow

- Up to three configurable levels of approval linked to separate user privileges (see *Agilent ChemStation Plus Security Pack – Electronic signatures and password settings* on page 33)
- Optional locking of runs after approval to prevent them from further modification (see *Agilent ChemStation Plus Security Pack – Electronic signatures and password settings* on page 33)
- New chromatogram view providing dynamic zoom and rescaling capabilities (*Agilent ChemStore C/S Interface* on page 15)
- Direct Read-access to ChemStation Method (see *Agilent ChemStation Plus Security Pack – Audit and Change Document* on page 36)
- Variables in advanced queries for operator names and dates (see *Agilent ChemStore C/S – Working with Agilent ChemStore C/S* on page 10)
- New database field for area% results from ChemStation

## Reporting

- Powerful custom calculator for advanced calculations, reporting and charting of calculation results, based on fully versioned calculation templates (see *ChemStore C/S – Working with Agilent ChemStore C/S, Custom calculations* on page 12)

- Optional peak performance calculation per-run or sequence line (see *ChemStore C/S – Reporting* on page 14)

## Open system connectivity

- File-less LIMS interface (see *ChemStore C/S – LIMS Connectivity* on page 18)

## Administration

- Email notification enhancements (see *Agilent ChemStation Plus Security Pack – E-Mail Notification* on page 37)
- Configurable command line access (see *ChemStation Plus Security Pack – User Management and Application Security* on page 28)

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It provides a means to easily organize, review and approve analytical data based on study and sample information. Agilent ChemStore C/S supports the users' data review process offering statistically result summaries, flexible control charts, cross-sample reports and documented data archiving and restoring. These services also aid users in doing on-going system suitability testing. The Agilent ChemStore C/S server database can be used as a single place for data storage for all analytical data including methods, sequences and the raw data. This data storage also

satisfies the requirements for data handling in a regulated environment including the detailed requirements of the U.S. food and drug administration for electronic records and electronic signatures, known as 21 CFR Part 11.

Agilent ChemStore C/S is available in two different configurations:

### • Agilent ChemStore C/S standalone database

This provides a low cost, easy-to-use, entry-level database module which integrates with a single Agilent ChemStation workstation. Very limited maintenance support is required and for users with advanced knowledge of the Windows XP or Windows 2000 operation system, the user can maintain it. This entry-level database module is for storage of all raw data in single database to ensure full data integrity. The file format adheres to a common standard, which is used by many other applications, for example, MS Access.

### • Agilent ChemStore C/S server Oracle® database client/server system

This client/server system is based on an Oracle database running on a Windows 2000 server together with multiple Agilent ChemStations and/or Agilent ChemStore C/S review clients. It provides enhanced data security and data integrity, distributed processing, as well as the ability to store raw data, methods and sequence files within the database. This configuration reflects best the

---

regulatory needs for electronic records and ensures full data integrity and traceability.

Based on standard database features, Agilent ChemStore C/S offers functionality which focuses on the user's needs for fast, secure and traceable handling of chromatographic data:

- User-defined or automated transfer of selected data from the Agilent ChemStation into the Agilent ChemStore database.
- Define, edit and manage "studies" as the underlying storage format.
- Manage or restrict data in studies by assigning access only to authorized users.
- Create database queries graphically without the need for any knowledge of the language.
- Review entire sets of data across instruments and studies, that several sequences in a fast and easy manner.
- Create additional filters and selection criteria to produce adequate subsets of the study in order to best sort the data and optimize the performance.
- Complete audit traceability by individual log-ins and complete documentation within the database including authorization failures.
- Security check of all files that have been transferred over the network from the ChemStation application to the ChemStore database application and back. Whenever a corruption of the

datafile is detected, the user receives an error message and the file is no longer available for modifications.

- Approve or reject runs after reviewing, following the rules for electronic signature.
- Ability to flag an arbitrary set of samples for reprocessing, and to initiate batch reprocessing of those samples on any Agilent ChemStation in a C/S network.
- Custom fields—User specified

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and reports.

- User-controlled fast and easy data export to other applications such as MS Excel®.
- Powerful and intuitive report generator based on MS Access runtime including most commonly used report templates.
- Architecture allows for off-line review. Can be installed as a data review client running on a separate PC without needing the Agilent ChemStation software.

- Data from non-Agilent chromatography systems may be included via the Agilent ChemStation AIA import capability.

- Agilent ChemStore C/S offers the possibility to start with an entry level solution, and to then upgrade when the data processing needs increase.

Laboratories can easily upgrade from one or more entry-level standalone systems to an Agilent ChemStore C/S server Oracle database client/server

environment. Previously stored data in entry-level databases can be easily migrated to the new server database. The user interface does not change, except that some additional items are available for administrators.

The built-in archive/delete tool allows for easy data transfer to disks and or media to free database space while keeping a complete audit-trail of all archiving and delete operations.

- Automatic archiving based on a set of configurable archive queries for easy database maintenance and administration.
- Open system connectivity using XML (Extensible Markup Language) for easy data exchange with other applications.
- Advanced email notification feature (C/S only). See page 37 for details.

# Agilent ChemStore C/S—System Requirements

## 1. Agilent ChemStore C/S standalone

### Hardware requirements

The following list shows the minimum hardware requirements for this application:

- 600-MHz Pentium III (Pentium IV recommend)
- 4 GByte of free hard disk space
- 128 MB RAM for single ChemStation instrument. 256 MB is recommended for best performance, for Windows minimum requirements
- 256 MB RAM for two ChemStation instruments. More is recommended for performance
- Display: 1024 × 768 pixels, 65-thousand colors

### Software requirements

The following list shows the minimum software requirements for this application:

- Windows 2000 Professional with Service Pack 4 or Windows XP Professional

- Service Pack 1a
- Agilent ChemStation revision A.10.01 or later
- Microsoft Internet Explorer 5.5 or later
- Microsoft data access components (MDAC) 2.8 will be installed on your system. If you already use a later version of MDAC, or for compatibility reasons require a previous version, please contact your Agilent support representative for compatibility information.

Typical runs use approximately 10 KB for a short report with four peaks, and use up to 300 KB per run for an extended performance report with 20 peaks. Table 1 helps calculate the amount of hard disk space requirements. Additional information on this topic may be found in the *Agilent ChemStore C/S Installation* manual and the *Concepts Guide*.

*Note:*

Standalone database size is limited to 800 MB due to some size limitations in the underlying file format. To ensure optimal performance for later data, Agilent strongly recommends not to exceed this database size limit. If a larger single database is required, Agilent recommends that the client/server version of the product be purchased. The client/server database uses Oracle, which allows for a much larger database. Additional standalone databases can be created via the Agilent ChemStore C/S utility.

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Number of peaks	Agilent ChemStation report style	Run length (minutes)	Approximate size per run (KB)
4	short	6	10
4	short	30	40
4	extended performance	6	80
20	short	6	190
20	extended performance	6	300

**Table 1**  
Client storage requirements for result only data storage

## 2. Agilent ChemStore C/S server Oracle® database system

### Client hardware requirements

The following list shows the minimum requirements for the **client** in a client/server installation.

- 600-MHz Pentium III (Pentium IV recommend)
- 4 GByte of free hard disk space
- 128 MB RAM for single ChemStation instrument. 256 MB is recommended for best performance, for Windows XP the minimum requirement
- 256 MB RAM for two ChemStation instruments (more is recommended for performance)
- Display: 1024 × 768; 65-thousand colors

### Client software requirements

- Windows 2000 Professional Service Pack 4 or Windows XP Professional Service Pack 1a
- Microsoft TCP/IP protocol
- Microsoft Internet Explorer 5.5 or later
- Microsoft data access components (MDAC) 2.8 will be installed on your system. If you already use a later version of MDAC, or require for compatibility reasons a previous version, please contact your Agilent support representative for compatibility information.
- Oracle 9i client version 9.2.0.3.0. (included with the ChemStore C/S server software)
- Agilent ChemStation version A.10.01 or higher (optional)
- A local or network printer must be installed and configured.

### Server hardware requirements

Agilent has optimized the performance of a ChemStation Plus client/server system to an average of 30 “concurrent” Agilent ChemStation/Agilent ChemStore Review clients, where concurrent clients are defined as clients connected to the central ChemStore C/S data organization system, that actively either spool data to the database or perform interactive queries (review client). Due to the nature of the application the impact of data retrieval is higher as

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can thus grow to approximately 30 acquisition clients with a maximum of 90 instruments. It is therefore

recommended to use a high speed dual processor system with sufficient RAM.

The minimum requirements for the **server** in a Client/Server installation are the following:

- 600-MHz Pentium III processor
- 512 MB RAM
- RAID SCSI controller
- 6 disk drives - 9 GB or larger—2 drives configured as a mirror set and 4 drives configured as a RAID-5 array
- Tape Device

interruptible Powersupply (S)

ive configuration yields one ed partition for the operation and application software and one large array for the se files.

### Server hardware configurations

The hardware requirements of the Agilent ChemStore C/S server will

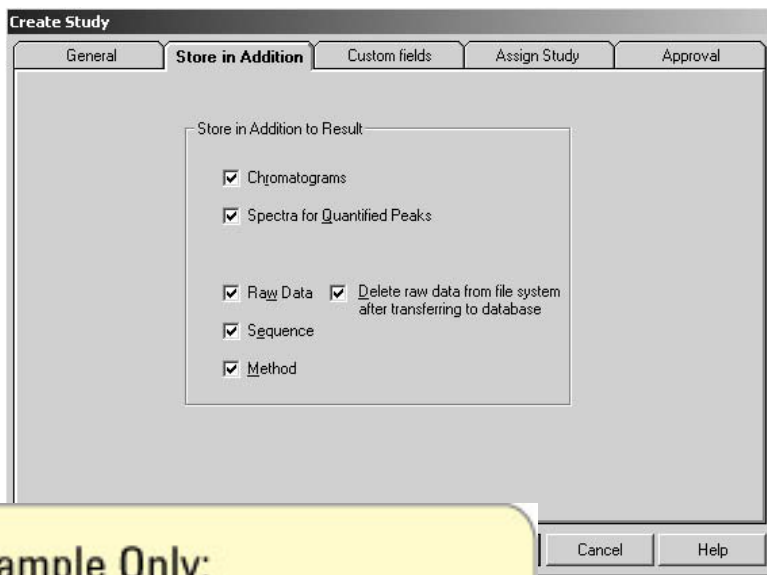
	Entry level	Standard level	Highend level
No. of concurrent review clients	1-5	1-15	> 15
Processor speed (GHz)	1	1	1
Number of processors	1	1	2
RAM (MB)	512	1024	2048
Number of RAID controllers	1	2	2
Disks for operating system	2 × 18 GB RAID 1	2 × 18 GB RAID 1 (Controller 1)	2 × 18 GB RAID 1 (Controller 1)
Disks for Oracle database	3 × 18 GB RAID 5 RAID 5	5 × 18 GB RAID 5 (Controller 2)	5 × 36 GB RAID 5, (Oracle Data, Contoller 2) 2 × 18 GB RAID 1 (Index Log Files, Rollback Segments, Controller 1)
Hot swappable drives	yes	yes	yes
Backup device	DAT/DLT tape drive	DAT/DLT tape drive	DAT/DLT tape drive
UPS	yes	yes	yes

**Table 2**  
Recommended server configurations for Agilent ChemStore C/S

vary based on the size of the database selected at installation time and the number of concurrent connections (the number of active instruments acquiring samples to the database and Agilent ChemStore C/S review clients) and the backup requirements for the server database. Table 2 shows three recommended server configurations. In a very small networked installation with less than three clients and no need for advanced security using RAID, the Chemstore C/S Oracle database can also run on a high-end PC using Microsoft Windows 2000 software as operating system.

*Note:*

Planning the server disk configuration is very important. 12 GByte (for small data) or 54 GByte (for large data) hard disk, RAID 5 configuration is recommended. Using hard disk configuration (redundancy and striping) yields less free hard disk space than RAID 0 (no redundancy). For example, 3 disks of 9 GByte each using RAID 5 yields 18 GBytes while using RAID 0 yields 27 GByte. RAID 5 is recommended for maximum performance and protection of your data. For backup operation of the database, the required disk space must be duplicated, that is a 54 GByte RAID 5 configuration should have an additional 54 GByte of disk space available for database backup. When calculating server memory requirements, calculate 8 MB of additional memory for each Agilent ChemStore C/S client. For more details on setup and



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### Server software requirements

- Windows 2000 Server with Service Pack 4
- Microsoft TCP/IP network protocol
- Microsoft Internet Explorer 5.5 or later (for admin client only)
- Internet Information Server version 3 or greater (IIS is integrated into Windows 2000 Server)
- Oracle 9i Standard Edition version 9.2.0.3.0 (included with ChemStore C/S server software)

database

### Database size

Database size is selected at installation time and should be given careful consideration as this will affect the total number of runs which can be accessed online and the frequency of archive/dearchive operations. Archive with delete (to recover run space in the database) or dearchive operations (to access run data online). At installation time you can either select from the preconfigured databases configurations listed in table 3, or have a customized configuration.

Database configuration	Approx. no. of runs	Database size
small	≤ 7500	4 GByte
medium	≤ 25000	10 GByte
large	> 25000	40 GByte

**Table 3**  
**Database configurations**

*Note:* The custom database configuration must be planned as a project with Agilent database consulting specialists prior to system installation. The size of the Agilent ChemStore C/S database is based on an Agilent ChemStore C/S system which has an average distribution of all Agilent ChemStation 2D and 3D techniques. Also, all *Store in Addition* checkboxes are enabled for all studies, as shown in figure 1. The space requirements for runs stored in the Agilent ChemStore C/S database will vary depending on the environment. A run is defined as a single set of results produced from a single sample acquisition. The data is reprocessed by an Agilent ChemStation which has been transferred and stored in the Agilent ChemStore C/S database.

The actual amount of space consumed by each run in an Agilent ChemStore C/S database will vary depending on:

- the *Store in Addition to Result* settings of the study to which the run is assigned (table 4), and
- the technique and complexity (numbers of peaks, Agilent ChemStation reports, custom fields, and so on) of your chromatography for that run.
- For details on the size of raw data files by technique,

- Retention time locking software, add-on module for Agilent ChemStation for gas chromatography,
- Agilent ChemStation for liquid chromatography, revision A.10.01 or later,
- Gel permeation chromatography software add-on module for the Agilent ChemStation for LC,
- Agilent ChemStation for capillary electrophoresis, revision A.10.01 or later,
- Agilent ChemStation for liquid chromatography mass selective detection, revision A.10.01 or

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- Agilent ChemStation for analog acquisition, revision A.10.01 or later,
- Agilent ChemStation for capillary electrophoresis mass selective detection, revision A.10.01 or later,
- Agilent ChemAccess C/S remote instrument control revision A.02.01, and
- Agilent ChemStation Plus Method Validation Pack A.02.01.

Store in Addition	Description
Chromatograms	Stores all available chromatograms (from each detector and/or signal)
Spectra for quantified peaks	Stores spectra from all peaks that have been identified and quantified as compounds in the calibration table.
Raw data	Stores the acquired data in addition to the calculated result. <i>Note:</i> This setting has a significant effect on the amount of storage space required for each run in the ChemStore C/S database. For example ChemStation data which is created from 3D techniques such as a liquid chromatography diode array detector will require more storage space than a 2D technique such as gas chromatography.
Sequence	Stores the ChemStation sequence.
Method	Stores the ChemStation method

**Table 4**  
**Store in Addition study settings**

Technique	Average file size (kB)
2D GC/LC	50
3D LC	60
3D LC/MS	750
3D CE	600

**Table 5**  
**Average raw data file size by technique**

# Agilent ChemStore C/S — Working with Agilent ChemStore C/S

## 1. Data transfer

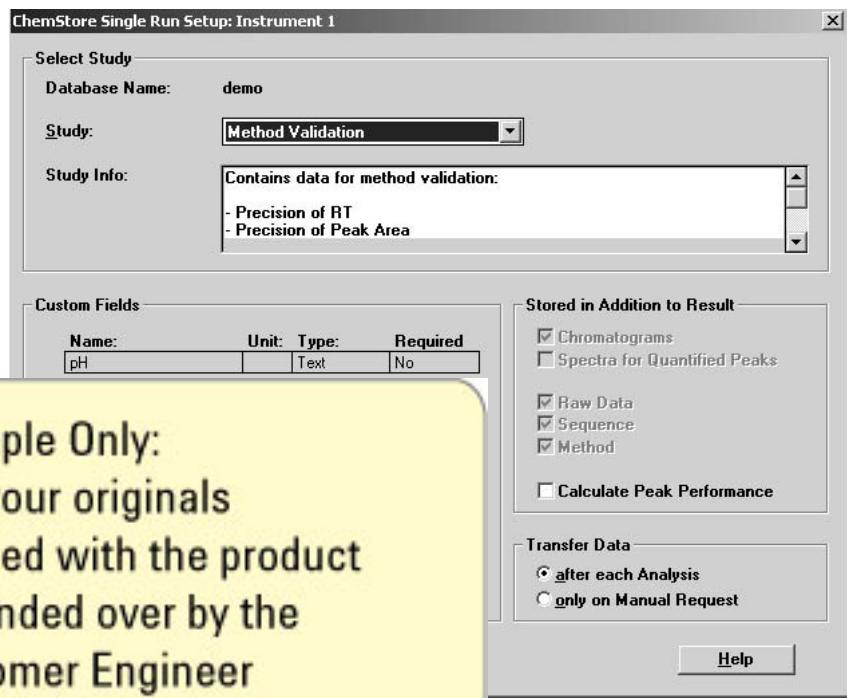
The Agilent ChemStation Plus concept consists of different software components designed for the various tasks in the chromatographic laboratory. The Agilent ChemStation manages data acquisition and data analysis, and the Agilent ChemStore C/S database offers advanced data and result management along with sample information such as data organization, result calculations, and archiving. This offers a clear separation of duties and advanced result management. The Agilent ChemStore C/S offers unmatched data security and traceability by providing a complete data history — Results in ChemStore can only be reviewed or after review completion, locked and pending for archival, while results in ChemStation are under rework. It is therefore very important to have a secure and documented data transfer between the software application. The specifications will offer a detailed outline of the data transfer including security measures for both directions. To further manifest this separation between rework and review, results can be locked from further modification when giving an approval.

### From Agilent ChemStation to ChemStore database

Agilent ChemStore C/S offers two modes of data transfer from the Agilent ChemStation into the Agilent ChemStore C/S database –

- interactive mode and
- automated mode.

Figure 2 shows the interactive mode.



Data transfer setup screen in the Agilent ChemStation

### Interactive mode

Users perform the transfer manually from the Agilent ChemStation menu item in “Data Analysis View” or use the batch review interface of the Agilent ChemStation. This mode of operation is useful for analysts who wish to perform a first pass data review from the Agilent ChemStation data analysis view before transferring the approved results to the database.

### Automated mode

Results are transferred automatically to the database at the end of each run. This mode ensures that all analytical data are transferred into the Agilent ChemStore C/S server database and are protected from unauthorized modification. If the same sample injection is reanalyzed and then transferred, a new version of the result data is

created, together with an entry in the audit trail of the Agilent ChemStore C/S database, thus ensuring a full history of the injection.

### File security during data transfer

Each file that is transferred over the network from the ChemStation to the ChemStore database or back is protected with a hash value. The application software automatically calculates the hash value prior to any data transfer using a 24 character value based on the RSA Data Security, Inc, MD 5™ message digest algorithm. The hash value is stored with the data file. Whenever this data file is transferred over the network, e.g. for a reanalysis cycle, the same message algorithm calculates the hash value of

the current file and compares it with the stored value. Any difference is reported as an error and the data transfer is interrupted.

### Assignment of studies and custom field information

Runs are stored in studies which form the top level hierarchical element of the Agilent ChemStore C/S database similar to a drawer in a cabinet. Study access is restricted to users that were explicitly granted the permission to access the data inside a study. Users must be assigned to a study in order to review data or spool data into a file. The amount of result data that is stored in the ChemStore C/S database is on a per study basis. For the transfer of a set of data, users can also include chromatograms, spectra, and the raw data and sequence file used to produce those results.

Custom fields allow additional information or result fields to be linked to each set of results ("run"). They are used to store additional information that is not accessible from the Agilent ChemStation method or results, that is, information which may reflect other measurements (for example, LIMS ID, sample pH, patient weight, dosage, and so on) or may be used to organize the data (for example, the identification code of the test patient from whom a serum sample was obtained). These custom fields may be configured as "required" or "optional". For the former, a value must be specified before results can be transferred to the database or a sequence can

be executed. Custom fields can also be used in later queries for reports, custom calculations or charts.

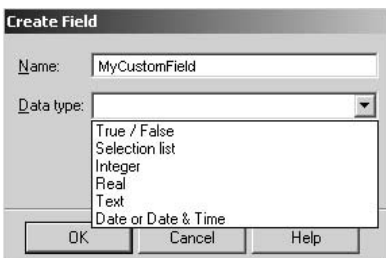
### Study and custom field configuration

A custom field and its type are defined globally per database as shown in figure 3. The available field types are:

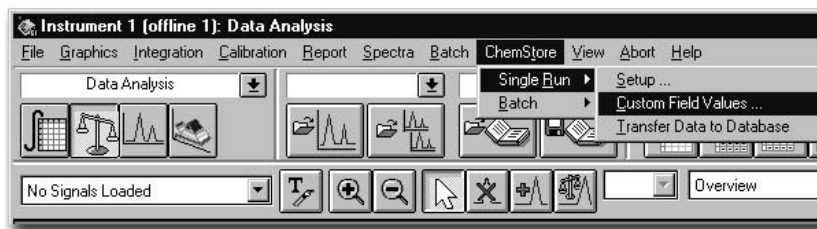
- True/False selection
- Configurable selection list
- Integer value
- Real value

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fields can be flagged as "required"



**Figure 3**  
Creating a custom field



**Figure 4**  
Data transfer setup screen in the Agilent ChemStation

or a default value as well upper and lower limits can be specified.

Custom field values are entered before the single sample or sequence acquisition:

- Single sample/manual operation: Study and custom field values are entered by a "single run" Agilent ChemStation menu item (figure 4).
- Sequence operation: Study and custom field values are specified per sequence line and stored with the sequence.

Agilent ChemStore C/S data capabilities, the lab manager or quality control person can review data generated on multiple instruments throughout the lab. Results can be approved, rejected, or assigned for rework in the Agilent ChemStation (see *From database to the Agilent ChemStation*).

### ChemStore spooler – Managing data transfer from Agilent ChemStation to Agilent ChemStore C/S

To ensure optimum performance of the Agilent ChemStation, a background spooler takes care of a secure result transfer from the Agilent ChemStation data into the Agilent ChemStore C/S database.

This approach has several advantages, including

- releasing the Agilent ChemStation to go on with other tasks quickly while the transfer continues in the background and
- guarding against data loss in case the database insert operation fails or the network is down.

### From database to the Agilent ChemStation

Runs which require rework, for example integration, can be transferred from the database to ChemStation. Agilent ChemStation C/S creates an Agilent batch to ensure a continuous operation. The setup batch submission is as follows:

1. Create the batch request from the Agilent ChemStore C/S review client by marking the runs for transfer in the user interface. An authorized user configures the transfer details in an interactive pop-up window (figure 5). These include
  - assigning the run data to one or, in case of several runs, to more than one user for reanalysis on a per run basis,
  - optionally transferring the method with the data (including the choice between all versions of the method), and
  - entering a comment with each run transfer that will be displayed to the Agilent ChemStation operator.
2. Use the Agilent ChemStation *Load Batch from ChemStore*

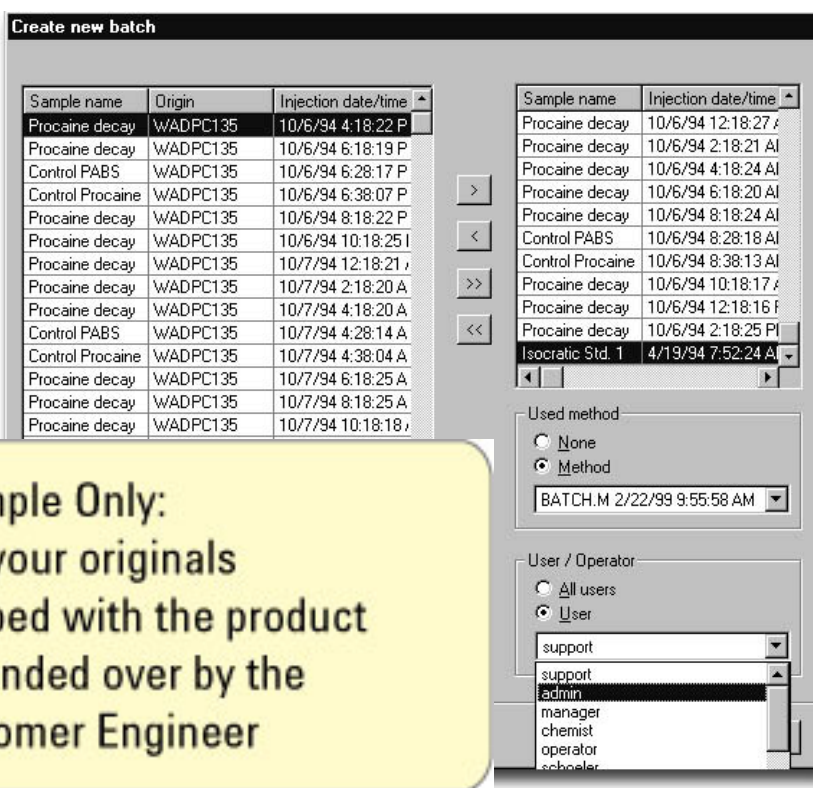


Figure 5  
Batch setup for data transfer from database to the Agilent ChemStation

menu item to select the desired batch from the pool of pending Agilent ChemStore C/S batches to download the runs to the Agilent ChemStation. The operator then reviews the data in the ChemStation batch review and makes the necessary changes. After completion of the review the modifications can be transferred to the database as new result versions.

### 2. Task flow in the review client

#### Retrieve and review sample data

The ChemStore C/S review client provides two user interfaces for

data review - the sample-centric *Sample* view and the compound-centric *Compound* view. Both views are further subdivided into a tabular display, with or without chromatograms and/or spectra, and a chart display for plotting sample- or compound-related data.

The task flow of Agilent ChemStore C/S is designed to support the laboratory's workflow and can be outlined as follows:

1. Select the database that contains the data you want to work with.
2. Extract the set of results you will work with. This is done via a database query and the results become the "current set

- of data”.
3. Perform any of the following tasks, in any order:
    - Review the results “by sample” or “by compound”. While reviewing the results, you may switch between any of several different data presentations (for example, a table, a chart, or plots of the chromatograms and or spectra). In addition, you may specify additional statistical computations to be done on the results and included in the tabular or graphical presentations.
    - Generate a report on the data in the set of data. You can select a set of report templates to be used, and you may customize those templates according to your needs or create new ones.
    - Export selected data to a file. The data can be sent to an Excel file or to an application that supports cut-and-paste in an appropriate format.
    - Execute custom calculations such as cross-run or cross-compound calculations or advanced statistical calculations. Pre-defined templates can be modified or new ones can be created. Modifications are stored as new template version. Calculation tables and charts of calculated values can be integrated into the report.
    - Set up a “batch” by marking runs whose data and method are to be transferred back to the Agilent ChemStation for re-analysis.
    - Filter or exclude any run in the current data set.
    - Approve or reject runs based on your result review. Both steps follow the FDA require-

ments for electronic signatures. The standard query builder of ChemStore C/S provides fast access to the commonly used database fields for fast and easy data retrieval. For more sophisticated queries the advanced query builder provides for access to all database fields, conditional query capabilities as well as the use of variables for the operator name (“currently logged on user”) and the date (for example “not older than 2 days”).

#### Performing statistics

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- number
- minimum
- maximum
- sum
- mean
- variance
- standard deviation
- relative standard deviation

In addition, *Regression Statistics* can also be used to calculate curves and statistics of two numerical columns. Curve types include:

- linear
- quadratic
- cubic
- logarithmic
- exponential
- power

The curve parameters for the curves and the residuals will be calculated and displayed. Residual curves can also be displayed as a part.

#### Mathematical expressions

Mathematical calculations can be performed on results using the built-in expression definition language (figure 7).

The *Expression Editor* offers the basic expression functions (addition, subtraction, division and multiplication) plus the following functions:

- exponential
- natural logarithm
- logarithm
- square
- square root

Statistics	Biphenyl			
	Amount	RT	Area	Height
Count	15	15	15	15
Sum	0.14	38.57	4074.03	559.70
Minimum	0.00536	2.56547	142.49	25.44
Maximum	0.01701	2.58024	452.50	58.34
Mean	0.00955	2.57133	271.60	37.31
Standard Deviation	0.0045	0.0051	127.4384	13.9228
Rel. Std. Dev. (%)	47.2374	0.1968	46.9210	37.3131
Variance	0.0000	0.0000	16240.5492	193.8437

**Figure 6**  
Summary statistics

## Custom calculations

The ChemStore C/S custom calculator provides all means to develop custom calculations that cannot be done with the simple expression builder. The custom calculator user interface for development of calculation templates is shown in figure 8. Calculation templates are fully versioned. The modification of an existing calculation template is stored as a new template. Only users with the appropriate permission have access to the custom calculator.

For a fast and easy development the calculator is equipped with editors:

- *Create Table* defines data items for the calculation
- *Create Subtable* defines subtables of data
- *Insert Column* allows to define columns that are populated with calculation results and can be used in further calculations
- *Define Variable* allows to specify variables (fixed values or calculation results) that can be used in further calculations
- *IF condition* defines conditional values, for example for limit checking, resulting in a configurable result output, such as “pass” or “fail”.
- *Format* defines the number format and precision of data items for reporting
- *Transpose* allows to transpose a table or subtable

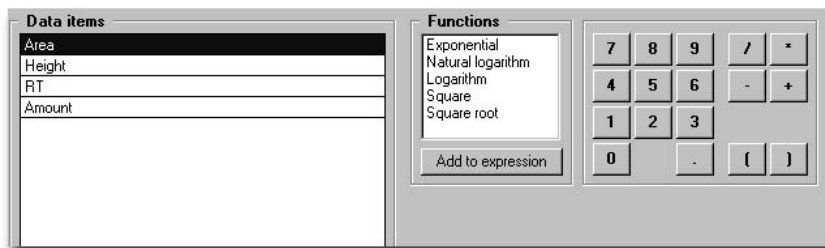
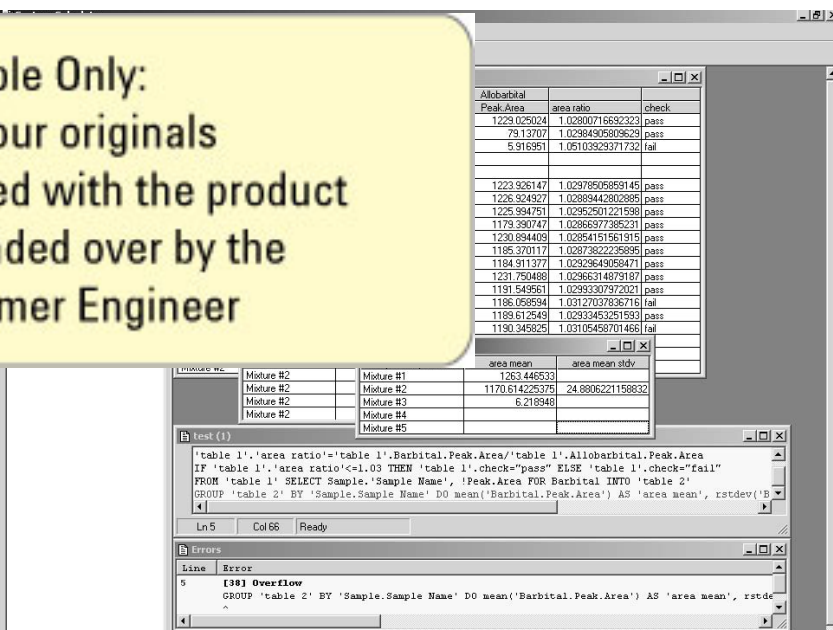


Figure 7  
Setup of custom expressions

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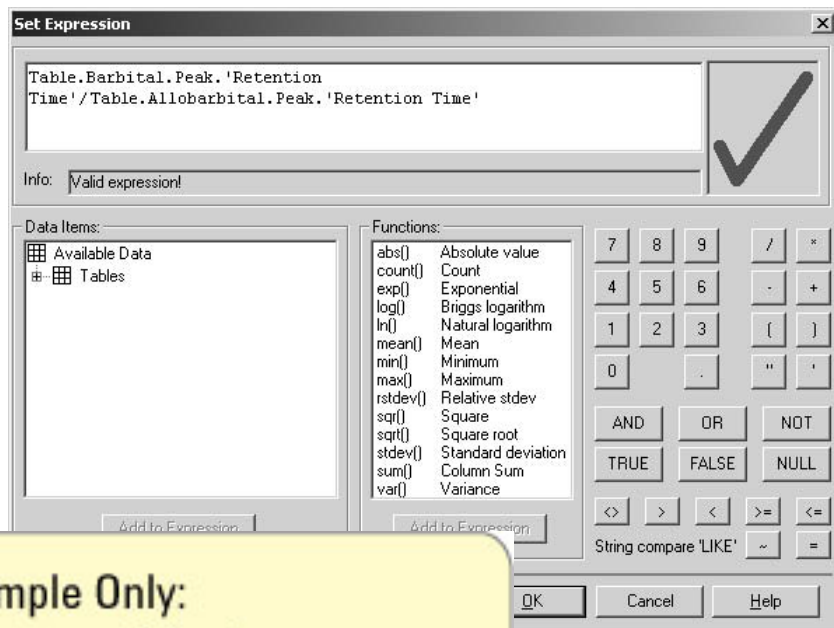
- *Group* allows to group by a specific data item and do statistical group calculations, such as
  - number of values (“count”),
  - maximum value,
  - mean value,
  - minimum value,
  - relative standard deviation,
  - standard deviation,
  - sum, and
  - variance.

The expression wizard (figure 9) is used for defining a calculation, which can be either an expression or condition. Calculations can be defined for all available columns or variables. It provides a set of arithmetical and statistical functions that can be used in conditions or expressions, these include:

- addition
- subtraction
- multiplication
- division
- absolute value
- count
- exponential
- logarithm
- natural logarithm
- mean value
- minimum
- maximum
- relative standard d
- square
- square root
- standard deviation
- sum
- variance

Multiple calculations can be defined within a single template based on any table or subtable.

All calculations are strictly column-based operations and easily allow any kind of cross-compound calculation, for example for the determination of relative retention times as required in some regulatory methods for confirmation of a successful identification or for calculating relative responses. The transpose wizard converts a table for doing cross-run calculations such as the comparison of results to a reference run. The group wizard provides for the ability of grouping a set of results by criteria



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serve as a data source for further calculations. The IF condition wizard integrates with the expression builder and can filter result data based on virtually any condition. The output can be reported according to the specific laboratory or regulatory requirements, for example for limit checking – a sample result lying outside of a specified interval can be flagged as “out of spec.”.

During the development the custom calculation is documented in a scripting window as shown in figure 8. This protocol is stored in the database as the calculation template. Each new version of a template is stored with version

ation. Optionally it can be led in the report to fully ment the calculation.

Any part of the calculation or the complete template can be tested on sample data obtained by a database query. Any error or inconsistency is identified and documented in the error window. The related calculation piece is highlighted in the protocol for convenient and simple troubleshooting.

Calculation result tables as well as charted calculation results can be integrated into ChemStore reports. The user may choose whether to base a report on the latest version of a calculation or any earlier one. The reporting capabilities of ChemStore C/S are outlined in the following section.

## Agilent ChemStore C/S — Reporting

---

Agilent ChemStore C/S offers a powerful report generator enabling users to easily create and generate final summary reports. The preview function helps to interactively develop the desired report without requiring test printouts. Agilent ChemStore C/S comes with a set of built-in templates to cover the most common needs for summary reporting. These templates can be used as a starting point to build customized reports.

Following is a list of reports:

- *Analysis Results*
- *Audit Trails* report
- *Compound Amount* for individual results
- *Instrument and*
- *Peak Details* report
- *Kinetic Decay* reports.
- *Sample Summary* reports with numeric tables of the result information.
- *Sequence summary* report—a complete report for GMP requirements including summary statistics, graphics of chromatograms and spectra and result charts with control limits for each compound type grouped by the sample type.
- *System Suitability* summary reports including statistics over replicate injections.

The following are key customizable features of the reporting

- display of the selection criteria of the query,
- display of all custom calculations that have been used in the data section of the report
- an overall report header displayed on each page that allows to include graphic items such as a company logo,
- table information,

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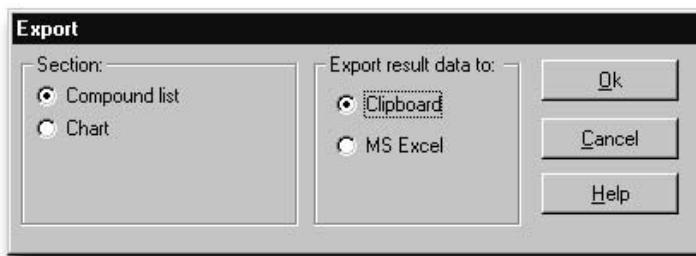
- one data section to group data logically, for example, around a vial number, a sample type or any other item that the user requires,
- restriction capabilities to focus on an adequate subset of the data, that is, one peak within a chromatogram, and
- statistical calculations selected interactively at any time during the data review from the ChemStore C/S user interface.
- inclusion of custom calculation result tables, charts of calculated values and full documentation of the custom calculations, including calculation formula and calculation errors.

The ChemStore C/S application offers an additional functionality to print the current view. This function gives access to an immediate printout of the actual screen including all graphics without any formatting or configuration tasks.

For system suitability reports the calculation of system suitability parameters can be triggered independently of the ChemStation method during sample or sequence run by enabling the “Calculate System Performance” checkmark on the run or sequence line (see page 2).

## Agilent ChemStore C/S — Data Export into Other Applications

Agilent ChemStore C/S allows an easy export of selected database information (selection by records and data fields) to third party applications (notably MS Excel). The user has control over which fields are included and in which order. This can be done based on queries or reports exporting data into the native file format. Agilent ChemStore C/S also offers clipboard cut-and-paste for both tabular and graphical data (figure 10). Report outputs can be in a file format allowing convenient publishing of reports, for example, HTML for internet and intranet publishing.



**Figure 10**  
Interactive data export from Agilent ChemStore C/S into other applications

ChemStore C/S allows printing in the following file formats:

- HTML format for review with an Internet browser (excluding graphics).
- CSV format for spreadsheet applications
- XML format as generic file-interface (excluding graphics)

## Agilent ChemStore

The Agilent ChemStore client offers the user "toolkits": data review and administration. The latter is described in the next section.

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Summary or regression statistics can be used. If regression statistics are being calculated, the regression chart and residual chart presentations replace it. Figure 11 is an example of a chart contained in the display area.

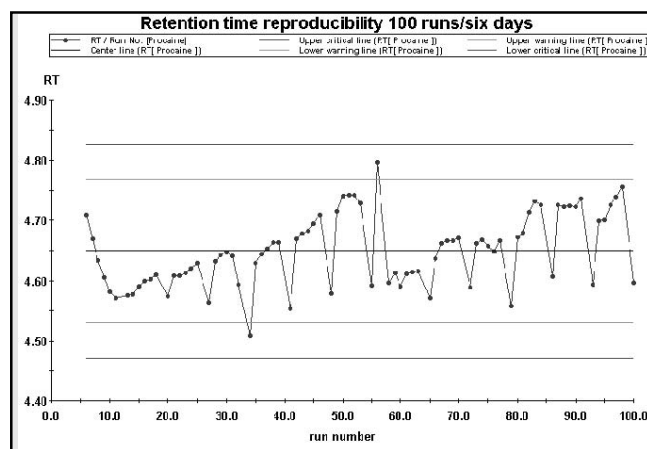
### Sample and compound review

Within the data review toolkit, the user has a choice of whether to see data organized by analysis (also referred to as "run" or "sample") or by compound. In the table layout view data is displayed in configurable tables, either sample- or compound-centric.

### Chromatogram/spectrum presentation

In the review layout view, the display area can contain both graphics and a table. The details differ for sample and compound review. The chromatogram viewer provides for dynamic zooming and rescaling capabilities, allowing a

presentation is available only if no



**Figure 11**  
Chart for retention time reproducibility with warning and critical limits

## Agilent ChemStore C/S — Security

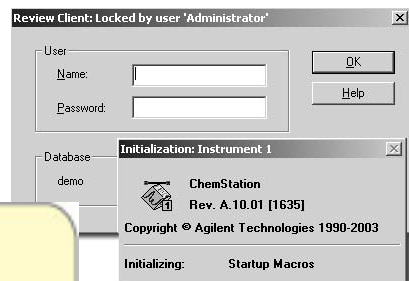
Data acquisition, data analysis and data review are password-protected. Each user must have a valid user-id and a password to log on to the application, as shown in figure 12. To be able to transfer data to the database the user must be logged on to the database. User validation is done on a per database level and always requires to enter a user name and a password. Permissions for several tasks like approval or archival of runs, creation of custom fields, report templates, calculation templates or studies can be assigned to each individual user. Four user group templates for permission rights are supplied with the client. They can be used as a starting point for the assignment of the permissions. Names and their security permissions are configured separately.

Agilent ChemStore C/S database. Users and their permissions can be imported from an existing database during creation of a new standalone database. In a client/server environment users are centrally managed in the Oracle database.

### Electronic signatures and password security

Agilent ChemStore C/S uses electronic signatures based on the application User-ID/password combination to uniquely identify the users and their signatures. In

*Minimum length* is the minimum acceptable length (in characters) of a password. *Password validity* is the length of time (in days) over which the password remains valid. *Minimum password recycle* is the minimum number of new, unique passwords that a user must use before a password can be used again.



12  
Password protection of the application  
review client

## Agilent ChemStore C/S

## and Recovery

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### Database administration

The review client provides the graphical user interface (GUI) through which the user can accomplish the following administrative tasks. Although the capabilities of the entry-level and client/server versions are to some extent different, the GUI is identical.

- Create a new database—(entry level database only),
- Compact (defragment) a database—(entry level database only),
- Create or modify a study or custom fields,
- Administer system settings,
- Administer users and security,
- Manual or automatic archive, delete and de-archive data (server-only),

- Assign studies to users,
- Email notification for example on security violations (server-only).

The client/server version offers supplementary tools for administrators in the *Admin Client* to perform proper maintenance of the server database, archive/dearchive or archive/delete functions and other setup tasks. The Agilent ChemStore C/S *Admin Client* is a web-based application that can be run from any PC on the network. The *Admin Client* performs the following main tasks on the server database using a service running on the server.

- Schedule archive, dearchive and delete operations.
- Modify scheduled operations.
- View reports detailing pending operations.
- Review archive and dearchive history.
- View information about archives, runs and other objects, including a list of all runs in the archive unit.
- Execute archive, dearchive and delete operations immediately.
- Keep an audit trail of all archive and archive delete operations.
- Add and modify database connections to offer connection to a second Oracle database.

## Database backup and recovery

One of the most important IT routines is the implementation of a Backup and Restore concept. Backups and – equally as important – the ability to restore a backup are important tasks in order to protect business data and laboratory investments.

Agilent Technologies can provide assistance in creating, implement-

ing and testing a ChemStore C/S Server Backup and Restore strategy. This strategy should ideally be planned before the implementation but Agilent offers both, a service prior to the installation as well as a post implementation service.

For this purpose a ChemStore C/S Backup & Recovery strategy paper has been developed. With this strategy paper and by working with a customer's ChemStore C/S

administrator Agilent provides a consulting service to plan and implement the right backup and recovery strategy for your business.

With a working knowledge of implementing solutions Agilent uses software from Veritas called Veritas Backup Exec™ for Windows 2000, Backup Exec Agent for Oracle™ and Backup Exec Intelligent Disaster Recovery.

## Agilent ChemStore

The client-server version for manual or automatic runs present in the a separate file on disk

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adding wildcards and relative (for example, runs “older x days”). For performance the number of clauses can be defined for automated archival is restricted to 10.

## Manual archiving

Manual archiving is done from the “Archive/Delete” view in the ChemStore C/S review client and is based on the selected data set. Manual archiving requires the user to have the permission for archival. Individual runs or the whole set of runs are marked interactively for archival. These runs are then scheduled for the next archival operation on the server.

## Automatic archival

An administrator with archival permission can set up a list of individual archive queries for automatic archiving, which are executed at predefined time intervals. Each custom query is put together from a set of criteria, including for example, injection time, sample name, instrument

category (text, numeric values, date)

The screenshot shows the 'Create Archive Query' dialog box with the following fields: Name (testarchive1), Path (serverpath\folder1), File (testarchive), and a checkbox for 'Delete runs after archiving'. The 'Comment' field contains 'This is my first archive query'. The 'Query Condition' section shows a single clause: 'Study Name is equal 'Method Validation'' and 'Instrument Name is equal 'HP 1050 System 1''. The 'Schedule' section shows a frequency of 'every 1 Week(s)' and a first starting date of '22.11.2002' at '10:00:00'. Below the dialog box is the 'Automated Archive' table.

Name	Frequency	Scheduled At	Creator	Status
archivequery1	3 monthly	2003-04-01	Administrator	Active
archivequery2	1 daily	2002-12-20	Bernhard Etrich	Active
archivequery3	1 weekly	2003-03-01	Administrator	Inactive
archivequery4	10 daily	2003-04-01	Administrator	Active
archivequery5	3 weekly	2003-04-01	Ute Bober	Active

**Figure 13**  
Setup of automatic archive queries

---

Each archive query is stored under a unique user-defined name and can be executed based on a configurable time interval (per query), for example, daily, weekly, monthly or in conjunction with a counter such as every x days. A test functions allows the user to obtain information on the number of runs that the query returns at the moment with the given query condition. For each archive query the name and path for the archive unit have to be specified. The

filename for the automatic archive file is appended with the archival date, resulting in a file name format “<filename>-yyyy-mm-dd”. Each archive query can be disabled when not required permanently. After successful completion of the archive the data can be automatically deleted to create free space in the database.

Both manual and automatic archival require re-identification with user-ID and password.

A checksum-protected archive catalog file in XML format is generated with each archive unit, which contains detailed information about the content of the binary archive file. A generic archive interface provides a closer linkage to other applications for enhanced archive management (for example, archive management or hierarchical storage management systems).

## Agilent ChemS

ChemStation Plus c  
connected to a Lab  
Information Manag  
(LIMS). For this pu

Agilent ChemStation provides for a sample list import function to conveniently translate a work list from the LIMS into a ChemStation sequence. An instant, file-less result transfer back to the LIMS from the ChemStore C/S database (server only) is achieved through the integrated ChemStore C/S LIMS interface.

### Sample list import from LIMS

The sample list generated by the LIMS can be imported to the Agilent ChemStation as a ChemStation sequence in XML-file format. XML is a very portable and flexible protocol for inter-connectivity between systems.

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to the LIMS. Optionally additional two fields can be populated with LIMS-specific data.

### Result update to LIMS

ChemStore C/S provides for file-less access to all result data stored in the database as LIMS data (identified by the LIMS ID). This is achieved through a combination of read-access to all result data in the database as well as a controlled write-access for the LIMS. Prerequisite for results to be accessible by LIMS is the existence of a LIMS ID which is assigned per sequence line. In addition a LIMS notification may be used, which is tied to the

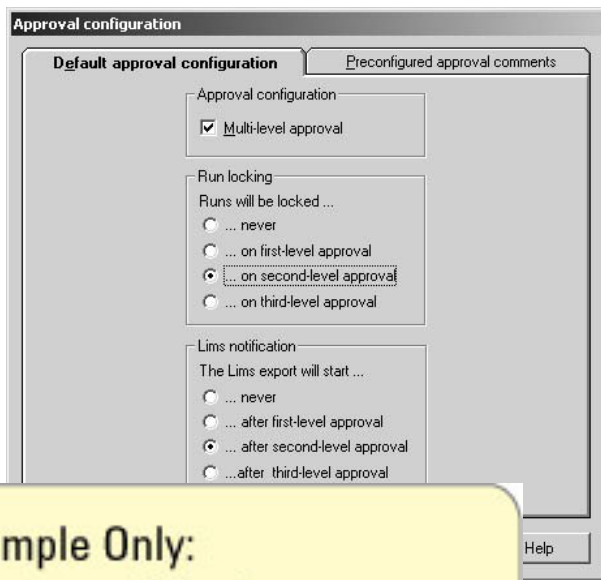
approval of data as shown in Figure 14. The administrator may decide which approval level is appropriate to initiate the LIMS transfer. In addition the LIMS can acknowledge data that was successfully transferred to LIMS to exclude it from future updates.

### Workflow

The workflow can be divided into five sequential activities shown below:

- 1 The sample list is generated by the LIMS system in an XML format
- 2 It is imported by the Agilent ChemStation and translated into a ChemStation sequence
- 3 Samples are analyzed, results are calculated and stored in the ChemStore C/S relational Oracle database

- 4 Information typically required by LIMS systems are instantly made accessible in the ChemStore C/S database (tied to the existence of the LIMS ID)
- 5 If enabled on the system or for a specific study, a LIMS notification is triggered upon the approval of data (as configured in the approval configuration console)
- 6 A program from the LIMS systems can scan a table in the database for a specific update flag to see if any new records are available for processing and can amend the data that it is not scanned in subsequent scans.



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## Agilent ChemStore C/S Installation and Upgrading

The standalone version of Agilent ChemStore C/S is user-installable from the ChemStore C/S CD-ROM and can be added to an existing ChemStation installation (Agilent ChemStation software family CD-ROM version A.10.01 or higher).

The Agilent ChemStore C/S Oracle client/server version includes :

- ChemStore C/S server software (included on the ChemStation Plus CD-ROM),
- Oracle 9i standard edition version 9.2.0.3.0 (included in ChemStore C/S server software on a set of separate CD-ROMs),

- ChemStation Plus CD-ROM, and
- ChemStore C/S client software (on ChemStation Plus CD-ROM).

### Agilent ChemStore C/S database migration

The Agilent ChemStore C/S system includes a migration utility which enables you to migrate your Agilent ChemStore C/S data in the following ways:

- Migrate Agilent ChemStore A.01.03 or B.0x.0x data (standalone) to Agilent ChemStore C/S B.03.01 (standalone).

- Migrate Agilent ChemStore C/S B.03.01 data to Agilent ChemStore C/S server data.

If you are currently running Agilent ChemStore A.01.03 on your system, and you wish to migrate your data to the Agilent ChemStore C/S server Oracle database, you will need to migrate in two steps. First migrate to the B.03.01 Agilent ChemStore C/S standalone database, then migrate from there to the Oracle database.

## Agilent ChemStore C/S — Product Options and Configurations

### Standalone version

The complete Agilent ChemStore C/S standalone software is provided on the Agilent ChemStation Plus CD-ROM as described in table 6a.

### Agilent ChemStore C/S server

The Agilent ChemStore C/S server product includes the ChemStation Plus CD-ROM and Oracle 9i revision 9.2.0.3.0 software on a separate CD-ROM offering one Oracle standard edition license. In addition an application-specific user license is required from Agilent for each user running a ChemStation client. Five application-specific named user licenses are included with the Agilent ChemStore C/S server. Refer to table 6b for

Description	Product No.
Software module to add Agilent ChemStore C/S to an existing ChemStation for GC, LC, LC/MSD, CE, CE/MSD or A/D.	G2181BA
License to use the ChemStore C/S database module on another computer. Must either be on the same order as G2181BA or the customer must supply the license number for the original software. Does not require ChemStation.	G2186BA
ChemStation Plus client upgrade software, upgrades a single ChemStation Plus client to the latest software revision. Requires valid software licenses and ChemStation upgrade software G1656A.	G1657A

**Table 6a**  
Agilent ChemStore C/S standalone version

	Product No.
C/S server software	G1410A
Named user licenses.	Qty: 1 per server
	G1411A
	Qty: (number of named users) – 5
ing	G2181BA
	Qty: 1 per server
r computer.	G2186BA
ine data acquisition	Qty: (number of clients connected to the server) – 1
sition ChemStation plus an additional online ChemStore license for offline data review	
ChemStation Plus client upgrade software, upgrades a single ChemStation Plus client to the latest software revision. Requires valid software licenses and ChemStation upgrade software G1656A.	G1657A
ChemStation Plus server upgrade software	G1655BA
Upgrades ChemStation Plus server software to the latest revision. Includes G1656A ChemStation software upgrade. Requires valid software license.	

**Table 6b**  
Agilent ChemStore C/S client/server version

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## Agilent ChemAccess C/S

### Product description

Agilent ChemAccess C/S is a client/server application which facilitates the secure and controlled integration of Agilent ChemStations into a networked environment by enabling users to:

- monitor and control instruments from any client on the network, for the following instrument modules:

HP 1090 Series and 1050 Series, Agilent 1100 Series, Agilent CE system, Agilent 5890, 6850, 6890 GC systems, Agilent 5972, 5973A and 5973N GC/MSD system, Agilent 1100 LC/MSD system, Agilent 35900 A/D converter

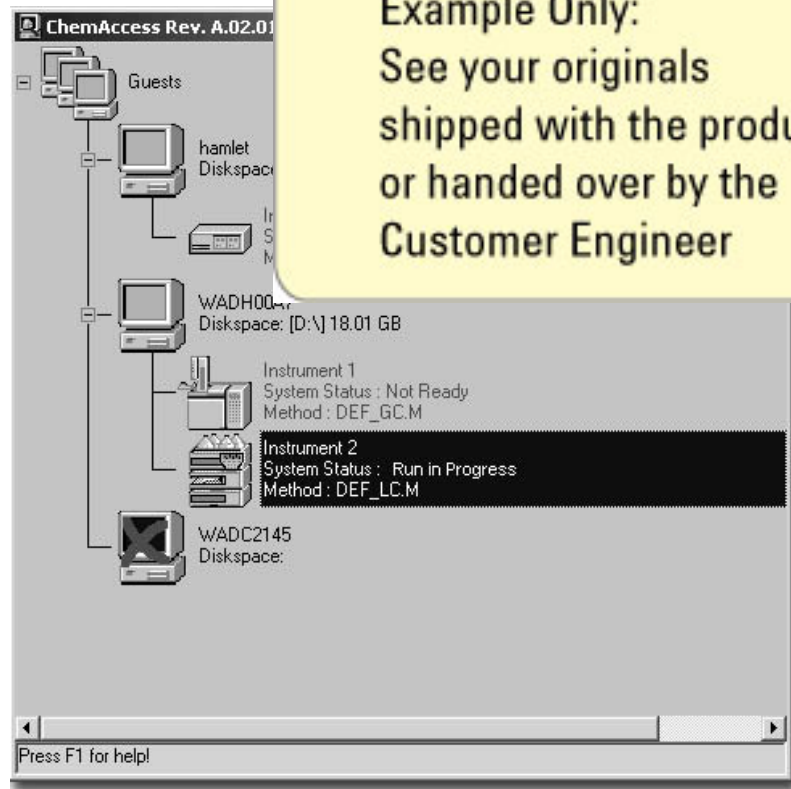
- provides flexible centralized data organization features which allows Agilent ChemStation files to be auto-

matically and securely stored onto the Agilent ChemAccess C/S server. This functionality is largely superseded when combining or adding Agilent ChemStore C/S to a Agilent ChemAccess C/S system.

An Agilent ChemAccess C/S data system contains Agilent ChemStation clients, the Agilent ChemAccess C/S software and a soft Windows NT server.

ChemAccess C/S is compatible with both the multi-technology Agilent ChemStation and analysis versions, enabling secure and cost effective remote monitoring control and data access from locations which are far away from the laboratory instrumentation.

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**Figure 15**  
Agilent ChemAccess C/S remote status and control user interface

### Remote status and monitoring and control

From any Agilent ChemAccess C/S client an authorized user can remotely perform the following tasks on a remote instrument:

- Start and stop the method or sequence currently running.
- Assign a method or sequence
- Real time plot of the instrument signals.
- Execute a remote Agilent ChemStation command.
- Monitor the status of the remote PC's resources (disk space, memory and software revisions).
- Monitor the status of the Agilent ChemStation and instrument modules. Details are shown in figure 15.

## Working with Agilent ChemAccess C/S

---

### Data storage and organization

Agilent ChemAccess C/S enables the Agilent ChemStation results (raw data, methods and sequences) to be securely stored on the Agilent ChemAccess Windows NT server. The results can be transferred automatically at the end of each run or interactively through the data analysis

view of the Agilent ChemStation. If the same results are retransferred to the server, Agilent ChemAccess C/S employs data versioning to ensure that an entire record of the analysis is recorded.

### Agilent ChemAccess C/S

#### Client hardware requirements

#### Agilent ChemStation and ChemAccess C/S

The PC client should meet the requirements as specified in *Agilent ChemStation Specifications* (Agilent publication number 5988-9925EN). In addition to these requirements further 8 MB memory is required for network connectivity software and Agilent ChemAccess C/S software.

#### Agilent ChemStation, ChemAccess and ChemStore C/S

Configure the client using the Agilent ChemStore C/S client hardware requirements specified in this document.

#### Client software requirements

The ChemAccess C/S client module can be added to the Agilent ChemStation. The ChemAccess C/S module is supported with the following ChemStation software packages:

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- Retention time locking software, add-on module for Agilent ChemStation for gas chromatography,
- Agilent ChemStation for liquid chromatography, revision A.08.04. to A.10.0x,
- Gel permeation chromatography software add-on module for the Agilent ChemStation for LC
- Agilent ChemStation for capillary electrophoresis, revision A.08.04. or later,
- Agilent ChemStation for liquid chromatography mass selective detection, revision A.08.04. to A.10.0x,
- Agilent ChemStation for analog signal acquisition, revision A.08.04. to A.10.0x, and
- Agilent ChemStation for capillary electrophoresis mass selective detection, revision A.08.04. or later.

Agilent ChemStation that is installed in an Agilent ChemAccess C/S system should conform to the following Agilent ChemStation and Windows software revisions:

- ChemStation for GC, LC, LC/MSD, CE and A/D revision A.08.04 to A.10.0x, on Windows NT 4.0 Service Pack 6a or Windows 2000 Service Pack 2-4
- GC/MSD ChemStation revision C.00.xx on Windows NT 4.0 Service Pack 6a.
- GC/MSD ChemStation revision D.00.xx on Windows NT 4.0 Service Pack 6a or Windows 2000 Service Pack 2.

#### Note:

Agilent ChemAccess C/S currently does not support the Agilent ChemStation for UV-visible systems.

### Server hardware requirements

Agilent ChemAccess C/S supports up to 15 “concurrent” Agilent ChemAccess clients, where concurrent is defined as a client connected to the Agilent ChemAccess C/S server which either transfers result data from the Agilent ChemStation to the server for data storage or performs remote real time plot. Recommended server configurations are listed in table 7.

*Note:*

For a ChemStation Plus system which has both ChemAccess and Agilent ChemStore modules, use Agilent ChemStore C/S requirements. Disk configuration may need to be customized to your laboratories on long term storage needs.

### Server software requirements

- Windows NT 4.0 with Service Pack 6a or Windows 2000 Service Pack 2
- Microsoft TCP/IP networking (supplied with Windows NT and Windows 2000).

	Entry level	Hi-end
Number of clients supported	1-10	1-15
Agilent NetServer model or equivalent	LC2000	LH3000
Processor speed (MHz)	933	1 GHz
Number of processors	1	1
		512 MB
		2 x 18 GB, 3 x 18 GB
		one and five
		yes
		1

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ChemAccess C/S

## Agilent ChemAccess C/S — Product Options and Configurations

The complete Agilent ChemAccess C/S software is provided on the Agilent ChemStation Plus CD-ROM. This includes the software listed in table 8.

Description	Product No.
ChemAccess server software for remote status, monitoring and control of 16-bit ChemStation. Includes 10-user licenses for 3D data analysis software and a 2-user license for the GC/MS data analysis software	G1494A
ChemAccess client software, 5-user license remote status, monitoring and control client software for 16-bit ChemStation.	G1495A
ChemStation Plus server upgrade software. Upgrades ChemStation Plus server software to the latest revision. Includes G1656A 16-bit ChemStation software upgrade. Requires valid software license.	G1655BA

**Table 8**  
**Agilent ChemAccess C/S software**

### 3. Agilent ChemStation Plus Security Pack

#### What's new?

Please refer to the section on new features in ChemStore C/S on page 2.

#### Product Description

The ChemStation Plus Security Pack is a module of the Agilent ChemStation Plus Series designed to support the requirements of 21 CFR Part 11. In the Agilent ChemStation the ChemStation Plus Security Pack modifies data analysis and provides advanced data management with regard to supporting the requirements for electronic records. It also of procedure to sign off runs w electronic signature. To supp the typical approval workflow regulated laboratory the Sec Pack optionally provides for levels of approval which can combined with run locking. offers an easy upgrade for an existing ChemStation install

and 5989-0848EN, respectively. The ChemStation Plus Security Pack is available as a standalone solution or in a fully integrated client server network connected to the ChemStore C/S server Oracle database. It provides full support of 21 CFR Part 11 by offering advanced data security, data integrity and full change documentation in audit-trails. Specifications of the ChemStore C/S database module are available in the ChemStore C/S section of this document.

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database. This database (determination of the database connection requires the log-on to the Windows operating system with a Windows administrator account) will store all raw, meta and result data. In addition, any recalculation of results in the ChemStation will automatically be recognized as a new result version and will be transferred to the database as a new version. This versioning assures that no data is ever lost or overwritten and that a complete chain of events is documented. If a new result version is generated, the user is forced to laboratory comment, tten to the audit trail.

data traceability, the Plus Security Pack books and audit trails nt who did what, when ese logbooks and audit er-independent and odified or deleted.

The Agilent ChemStation Plus Security Pack is compatible with the following ChemStation modules:

- Agilent ChemStation for GC, LC, A/D, CE, CE/MS and LC/MS for instrument control and data analysis
- Agilent ChemAccess C/S remote instrument control
- Agilent ChemStore C/S data organization and data storage module
- Agilent ChemStation Plus Method Validation Pack

The UV-Vis as well as GC/MS ChemStation offer separate solutions for 21 CFR Part 11. Please refer to the specifications of the UV ChemStation Security Pack and the MSD Security ChemStation included in publication number 5980-0337E

to the application. A user with administrative privileges can assign appropriate user permissions to other users within the ChemStation Plus software.

The ChemStation Plus Security Pack software allows to match user tasks in the laboratory with user roles in the software. It modifies the ChemStation operator rights, allowing to routinely operate the ChemStation application in the operator mode. For proper use and to achieve the best data security capabilities all users except those with administrative functions should utilize the ChemStation operator mode.

To achieve data integrity, all users are required to log on to a single

All data is in electronic format and capable of long-term storage through archive/restore as well as viewing and printing in human readable format.

Key product features of the ChemStation Plus Security Pack include storage of all chromatographic data in a relational database, secured through

- password protection to access the data,
- full data protection using Windows security and database security features,
- application protection with a mandatory log-in, consisting of both identification components - user-id and password,

- user management with individual user profiles and privileges for the application – independent of the user privileges assigned for the operating system,
- an application-specific session lock allowing to explicitly lock one ChemStation session while leaving a second instance running on the same PC, and
- a configurable time-based application lock to lock the current ChemStation or ChemStore session after a specified time, thus avoiding access to the
- A completely revised ChemStation operator access level which allows operating the entire application as ChemStation operator.
- A configurable access to the ChemStation commandline independent of the ChemStation user level, thus also preventing access for ChemStation managers.
- A modified batch review interface providing an automated user-independent data ver-
- Complete change control documentation for methods and manual integration changes.
- Four levels of audit-trails for data acquisition, data analysis application tasks and security violations.
- Electronic signatures for each result version following the guidelines of 21 CFR Part 11.
- Three configurable levels of approval.
- Optionally locking of runs upon the approval to prevent them from further modification.

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## ChemStation

### Client hardware requirements

The following list shows the minimum hardware requirements for this application:

- 600-MHz Pentium III (Pentium IV recommend)
- 4 GByte of free hard disk space
- 128 MB RAM for single ChemStation instrument. 256 MB is recommended for best performance, for Windows XP minimum requirement is 256 MB.
- 256 MB RAM for two ChemStation instruments (512 MB or more is recommended for best performance)
- Display: 1024 × 768; small fonts; 65-thousand colors

### Client software requirements

The following list shows the minimum software requirements for this application:

- Windows 2000 Professional with Service Pack 4 or Windows XP Profession Service Pack 1a
  - Agilent ChemStation revision A.10.01 or later
  - Microsoft Internet Explorer 5.5 or later
  - Microsoft data access components (MDAC) 2.8 will be installed on your system. If you already use a later version of MDAC, or require for compatibility reasons a previous version, please contact your Agilent support representative for compatibility information.
  - A local or network printer must be installed and configured.
  - The hard disk partition that is used for installation of Security Pack must be formatted with NTFS.
- The standalone database size is limited to 800 MB due to some

strict size limitations in the underlying file format. To ensure optimum performance for later data review Agilent strongly recommends not to exceed this database size limit. A configurable size-checking tool automatically launches a warning message when the specified size limit is reached.

If a larger single database is required, Agilent recommends that the client/server version of the product be purchased. The client/server database uses Oracle, which allows for a much larger database. Table 9 gives some data on the time required for downloading data from the standalone database into the active memory of the client. The time mainly depends on the size of the standalone database, the number of runs marked for download and

the performance characteristics of the computer. All runs were stored with raw data, methods, sequences, and all result versions. The PC used for the test was below the recommended configuration (Kayak PIII, 450 MHz, 128 MB, and no data acquisition running in the background).

Database Size	No. of peaks	No. of runs	No. of runs loaded from database	Time [s]
93986	2137	240	100	17
192048	4642	410	100	17
445826	22621	868	100	13
			683	76
1048472	36710	2203	100	13
			683	59

**Table 9**  
Run download time depending on the number of runs selected for download and the database size.

## Working with

### Result management

The ChemStation Plus Security Pack is designed to store ChemStation data in a relational database by transferring it as a post-data analysis spooling job to the database. Depending on the laboratory workflow the data analysis can also be separated from the acquisition. In this case only raw and meta data are automatically spooled to the database, without a first set of data analysis results (data is acquired in acquisition-only mode). The ChemStore C/S ODBC spooler is a proprietary tool managing the transfer and protecting data against loss, modification or damage in case of transfer problems or network errors.

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stored in a single database file. The subdirectory storing the database files is protected with Windows file security permissions and only allows write access for members of the Windows user group.

The application denies access to data without a valid ChemStation Plus user-id and password. Any attempt to access the data in the standalone database directly with another application such as MS Access fails as it requires a password/user-id combination that is strictly confidential and only known by Agilent. It is not known by or given to any Agilent customer or user of this product.

client-server installations of ChemStation Plus Security Pack prevent, uncontrolled access to data in the Oracle database without using the ChemStore user interface is virtually impossible. This is because users must have a valid Oracle user account and they must have access to the data dictionary describing the meaning and contents of the Oracle tables and table columns. The dictionary is only available from Agilent Technologies against a written Confidentiality Agreement and should not be available for application users. Overall the attempt to falsify or delete data requires the collaboration of the user and the database administrator that provides the direct database access. Sufficient security constraints need to be imposed within the organisation to prevent any uncontrolled modifications.

## Data storage

By default the the database stores the following data:

- calculation results of the ChemStation,
- contents of the ChemStation data directories; the \*.d directories including the chromatographic raw data files,
- current method used for data acquisition and data analysis,
- current sequence, if a sequence was run to acquire or analyze data,
- sequence, run and method logbooks,
- detector channel chromatograms as images according to the report configuration method, and
- apex spectra of all identified peaks in a chromatogram, when using a 3D detector.
- Optionally all peak performance parameters independent of the ChemStation method.

## Protection of temporary data files

The ChemStation uses a given data directory structure to store acquisition and result data. The ChemStation Plus Security Pack also protects this data. After completion of data acquisition and a first result calculation, by default the data transfer is immediately initialized through the ChemStore spooler and the \*.d directory with all its contents is deleted from the local hard disk (these default settings can only be modified by a user with administrative rights in

the database). From then on, the data security mechanisms of the database itself secure the data. The temporary directory where the database spooler stores intermediate data is protected using Windows NTFS file and folder security.

If a first pass review in the ChemStore review client results

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denying unauthorized access for operators.

## Configuration and data protection using Windows security features

For security reasons, a user must be a member of the Windows user

group *Administrators* or *Power Users* to access the configuration of the ChemStation Plus Security Pack. It restricts access to all data directories on the local PC with important information using the Windows users group privileges. The default configuration automatically sets all directory permissions and access limitations as part of the installation using the Windows groups "Users", "Power Users" or "Administrators". Each user has to be member of one of the groups.

Users must not be members of the Windows Administrators nor Power Users group. The membership to these groups should be dedicated for system administrators.

Table 10 gives an overview of the permission rights that are limited to members of the Windows Administrators and Power Users groups.

User task	Granted to members of Windows User group	Granted to member of Power Users or Administrators group
Create a new MS Access database	no	yes
Configure database Alias	no	yes
Access the ChemStore ODBC spooler to resume interrupted data transfer	yes	yes
Access to the selection list of available databases	no	yes

**Table 10**  
Tasks requiring membership in the Windows Administrators or Power Users group

Local directories storing relevant chromatographic data are also protected with Windows file and directory permissions. Table 11 gives an overview of the Windows permission rights on the data directories and files on the local hard disk. The first item in brackets displays the permission rights on the folder; the second item displays the individual file permission rights.

File path	Permission Windows Users	Permission Windows Administrators or Power Users	Directory/file owner	Data directory contents
\hpchem\chemstor\database	(W)(full)	(full)(RWXD),	All members of local Administrators or Power Users group	Contains database *.mdb file storing all raw and meta data
\hpchem\chemstor\spool	(WX)(full)	(full)(RWXD)	All members of local Administrators or Power Users group	Spooler jobs and data files
\hpchem\chemstor\hputil00.exe	none	(full)	All members of local Administrators or Power Users group	Access to ChemStore utility tool to create/copy and manage local database files
			All members of local Administrators or Power Users group	Stores data files re-loaded from ChemStore database to ChemStation batch review

*Note:*

Windows file security give any access to a directory for users who have access rights even if the user has the files in the folder.

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[le)] set by the ChemStation Plus  
D=delete, full=all permissions]

## ChemStation Plus

## Application Security

### User management and ChemStation Plus Security Pack user access rights

Security Pack provides a fully integrated user management that is independent of the Windows operating system. The user management covers both the ChemStation Plus data acquisition and data analysis tasks and the ChemStore C/S database data review privileges. The entire user administration itself is a user-privilege granted to administrators in the ChemStore C/S database. The ChemStation Plus Security Pack includes a modified ChemStation operator level allowing operators to perform all important acquisition and data analysis tasks for daily operations. Table 12 shows the most important changes in user

privileges compared to the standard ChemStation for data acquisition. The ChemStation Manager always has access to all tasks within the ChemStation with the exception of access to the ChemStation command line. Unlike the standard ChemStation this privilege can be

assigned individually and is not tied to any ChemStation user level (see figure 16). A detailed documentation of the data review user privileges in the ChemStore C/S database is in the ChemStore C/S concept guide.

User privilege	Security pack operator	ChemStation operator
Save acquisition method	no	no
Save data analysis method	yes	no
Load/run/save sequence	yes	yes
Modify acquisition parameter	yes	yes
Re-Integrate chromatograms manually	only in batch review	no
Change integration events	only in batch review	no
Recalibrate overview and peak summing	only in batch review	no
Recalibrate other	no	no
Apply method to data and print report	yes	yes
User-independent automated result versioning	yes	no
Access to tasks with manual result versioning	no	no

**Table 12**  
**Comparison of user privileges in the ChemStation Plus Security Pack and the standalone ChemStation**

## Application security

The Security Pack only allows users with a given user-ID to log on to the ChemStation Plus application, as shown in figure 12. Users need to be set up by the administrator to gain access. At initial login, users must specify their initial password in order to keep it unique to each user. Protecting the application

software from use during operation in a separate session. This lock function

- an interactive session should be enabled before leaving the instrument unattended, e.g. during shift changes
- for enhanced security, a time-based automatic session lock for other periods of short-term absence from the computer.

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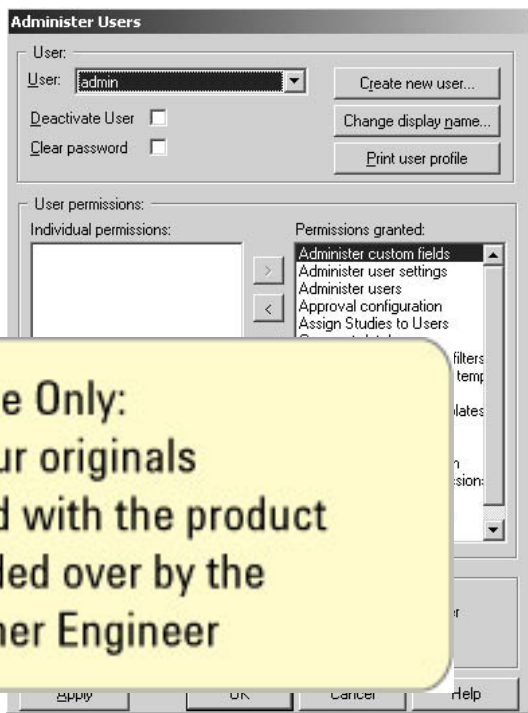


Figure 16  
User Management in ChemStation Plus Security Pack

The time-based session lock is configured centrally through users with administrative rights in the ChemStore C/S database, and is automatically applied on all connected ChemStation Plus clients. The session lock allows to lock each instrument session individually and independently, so users sharing computers with two or more instruments connected to one computer can operate with a clear user distinction and unique user identification. The name of the current user and the instrument session are always shown in the title bar. The instrument sessions can be locked either

- privately, allowing only the user who locked the session or an administrator to unlock it, or
- non-privately allowing all users with a valid user-ID in the data-

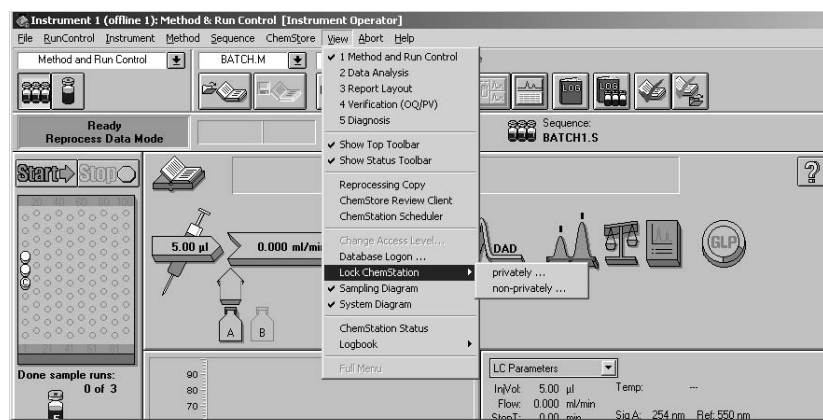


Figure 17  
Instrument session lock

base to unlock the session, for example during shift changes (figure 17). If a dialog is still open the application will automatically lock privately.

# ChemStation Plus Security Pack — Data Integrity, Automated Result Versioning and Data Reanalysis

## Data integrity

The Security Pack maintains full data integrity by storing all results along with the raw and meta data in a relational database as shown in figure 18.

## Result revision management

Daily work in the analytical laboratory often requires sample reanalysis. The ChemStation Plus Security Pack includes a result versioning that stores all recalculation results from one original injection as result versions. In addition, the application software includes a tool that automatically detects new results during the reanalysis process. This application-controlled automated process does not require any user intervention such as *Save Results* or similar action. It is completely user-independent and covers the following reanalysis steps:

- All functions in the batch review that calculate or change results such as reintegration, recalibration, method modifications (for example changing compound names) execution of predefined methods including manual reintegration
- In the data analysis view: Integrating, printing reports and recalibration excluding manual reintegration

Sequence reprocessing as well as all initial review tasks (loading a batch from disk, initial loading of a run into the interactive data analysis view) always create new result versions. These reanalysis tasks cover all activities of the ChemStation operator thus ensuring that all reanalysis steps at the ChemStation operator level include a user-independent versioning.

In addition, ChemStation Plus managers can perform manual result manipulation interactively in the *Data Analysis* view without using the batch review user interface. The user-independent revision management does not cover the manual reanalysis of results in the standard ChemStation data analysis view. The user creates new result versions in this review function using the manual *Transfer Data to Database* command (figure 19).

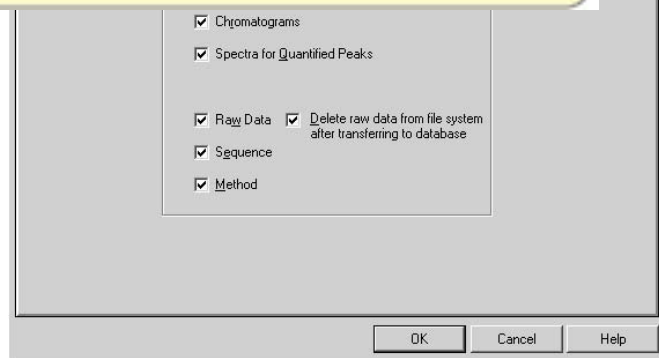
command to create a new result version:

- drawing a manual baseline,
- deleting a peak,
- tangent skimming of one peak,
- splitting a peak, and
- integrating manually with a negative baseline.

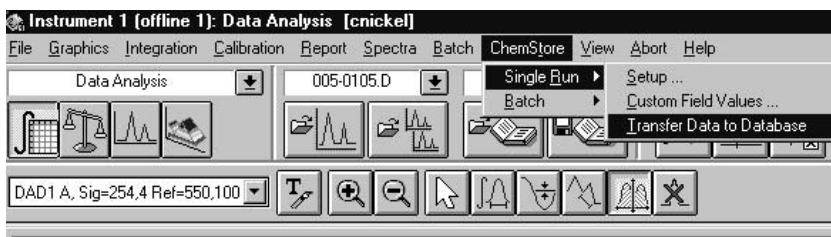
Access to tasks with a user-dependent creation of new results is the only difference in the result management between the ChemStation Security Pack manager level and the ChemStation

operator level. The result version in the database is the same for both user-independent and user-dependent

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**Figure 18**  
Default configuration of data storage in database



**Figure 19**  
Manual revision management

## User-independent, automated result version management

The data storage includes an application controlled version management that is based on the creation of a result reference file. Prior to reprocessing, the application software creates a binary result registry file called *save\_sec.reg* for each file. This *save\_sec* register is stored with the raw data. It contains numeric results of the result revision in a binary format such as amount, comparison time and so on. When a new result is calculated, the software automatically compares the new run result with the result in the register. If the results changed, the software detects the difference between the most recent and the current result and creates a new result version.

For proper documentation of the changes, the application software creates a second file in a human readable format that stores the results of the comparison and documents the changes. The file is named *sec\_trac.txt* and is stored along with the raw data in the \*.d subdirectory, as shown in figure 20. Both the registry and the text file are also stored in the database along with the raw data and they can be restored to disk with the data file, if necessary. These changes including manual integration events are also documented in the Manual Integration Events section of the ChemStore audit-trail as shown in figure 21. The audit trail as well as the *sec\_trac.txt* can be used in order to regenerate the result from raw and meta data at any time, for

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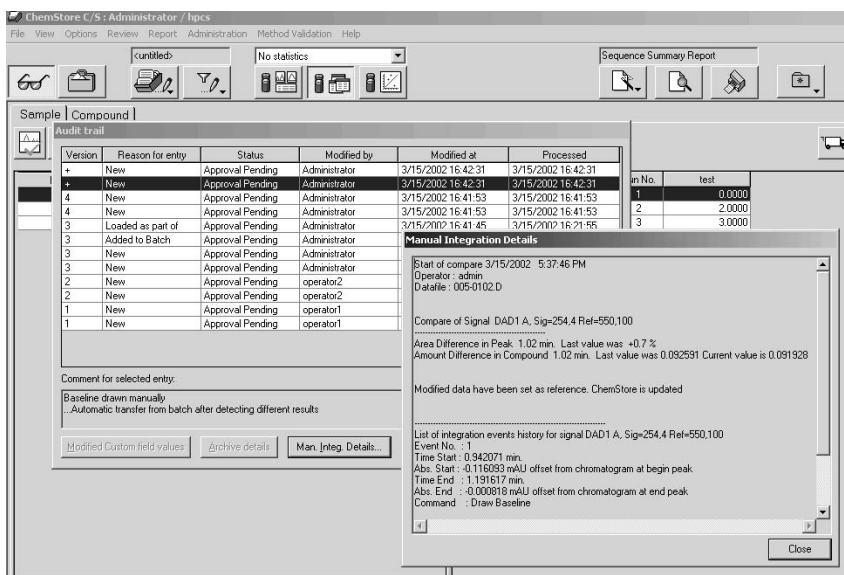
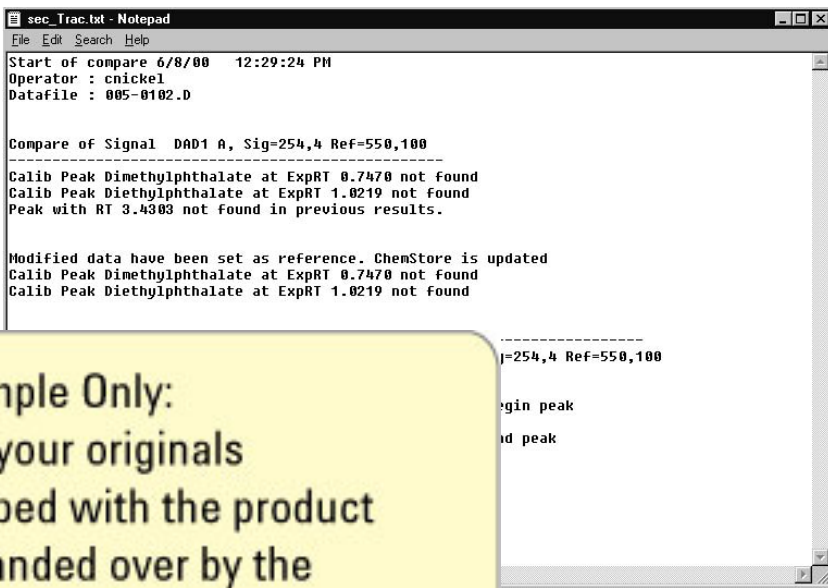


Figure 21  
Manual integration events documented in ChemStore run audit-trail

example in an audit situation (see also the application note “Handling of Electronic records with ChemStation Plus” publication number 5988-9643EN, which is

available under a confidentiality agreement).

## ChemStation Plus Security Pack—Graphical Result Review and Calculation

### Summary of version management in the ChemStation Plus Security Pack

Each time a new result is calculated in the ChemStation, the application compares the values with the result values of the last reprocessed result copy. If it detects a difference, it automatically initializes the data storage in

the database. Each data transfer of new results creates a new version entry in the database so that no data is ever overwritten. The versioning also assures that no “data” is lost and that a complete “chain of events” is documented. This ensures full data integrity and traceability.

### Agilent ChemStation

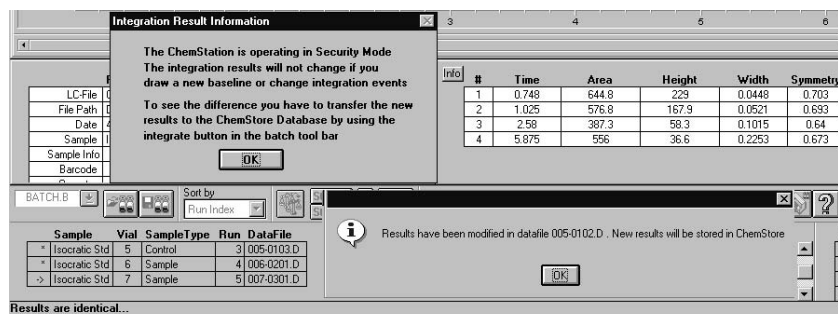
The graphical result review interface allows the user to inspect the results of the chromatogram and to check the integrity of the data. This is done in the ChemStore review client. If any further rework is required the data is submitted to the ChemStation batch review user interface for data reanalysis. In batch review the ChemStation Plus Security Pack allows splitting the review into a working and a

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This is done by setting new integration events and applying manual events such as baseline drawings and others without an immediate transfer to the database. The transfer is initiated automatically as soon as the user has finished his work and decides

### Review and Calculation

calculate the results with the settings by moving to the run or starting an automated result recalculation (figure 22). As soon as new results are created, the result transfer to the database is performed either for the single run, or if starting an automated result recalculation, for all reprocessed runs. During the transfer of manually integrated data the user is prompted for a mandatory comment that is written to the results audit trail. The comment can be either a selection from a set of predefined comments or a free text or a combination of both. After finishing the data reanalysis and closing the batch review interface, the temporary files will be deleted from the local hard disk.



**Figure 22**  
Result calculation and automated versioning

## ChemStation Plus Security Pack—Electronic Signatures and Password Security

21 CFR Part 11 permits the use of electronic signatures if the application ensures data integrity, data security and full audit-trail documentation. If an electronic signature is supposed to be equivalent to a handwritten signature it must contain at least two distinct identification components such as an identification code and a password.

### Approval of results

The ChemStation Plus Security Pack protects all activities that create, modify or delete records with user privileges and electronic signatures. Signing runs for approval is a privilege that can be configured and granted by a system administrator and is therefore limited to certain users. Signing runs for approval and rejection always prompts for a re-identification and password confirmation of the signer for each run, plus a mandatory comment for the sign off, as shown in figure 23. The signer has to be the currently logged-on user.

ChemStation Plus provides three levels of approval tied to two separate user permissions to support the typical approval workflow in an analytical laboratory. It can be configured on a study level whether multiple approval levels should be applied or not. The approval configuration is part of the study settings. For new studies the settings from the global approval configuration template are copied to the study. The approval configuration is shown in figure 24.

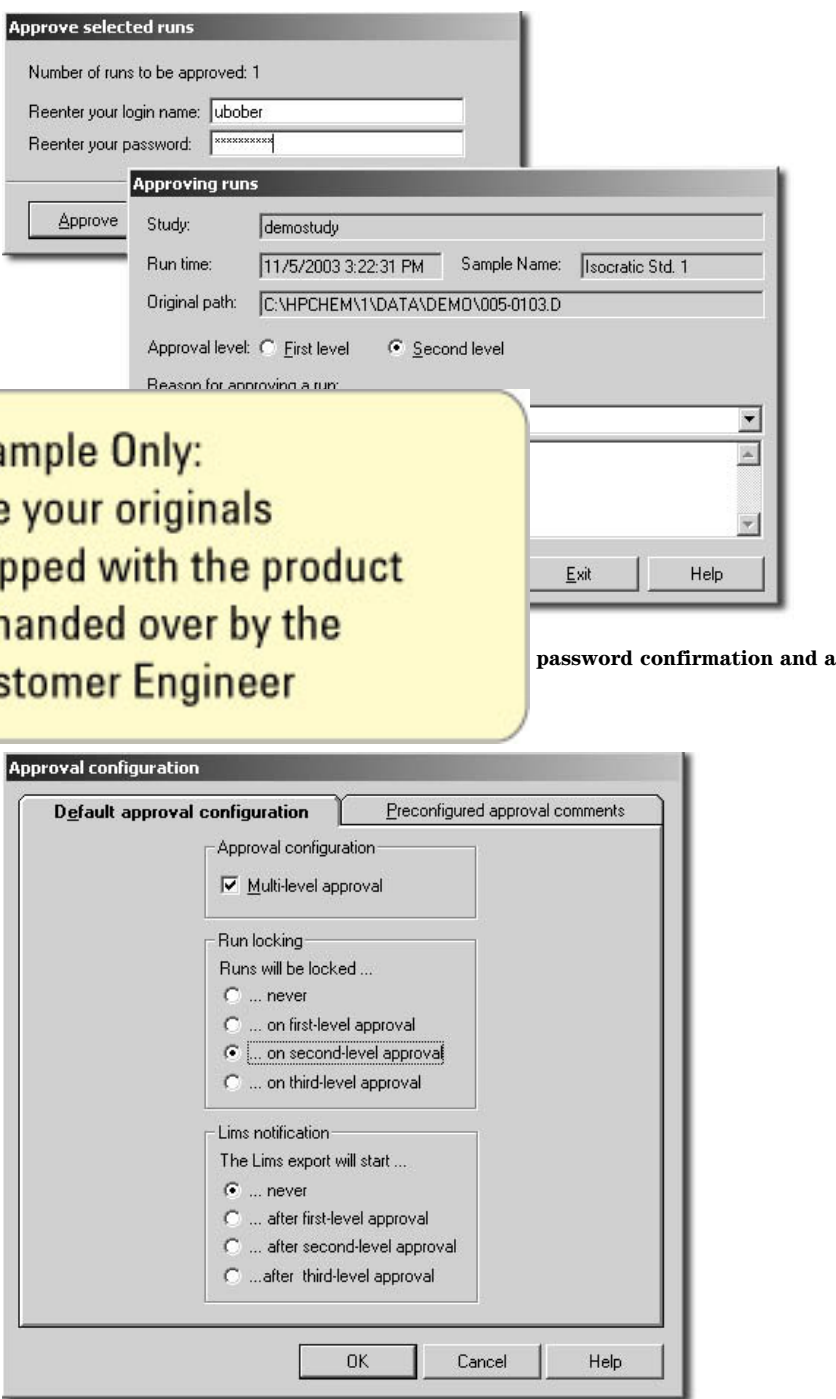


Figure 24  
Global approval configuration template

The operator will typically give the first level approval when reviewing his results. To allow for peer reviews the application supports multiple first level approvals. The second level approval lies in the responsibility of the laboratory manager when signing off the results and prevents a signed run from further first level approvals, unless the run is rejected. The third level approval (equals a 2nd second level approval) can serve as the final sign-off by the quality department. It requires a user to have the second level approval permission. A third level approval no further actions can be applied to a run is rejected. Optionally a user can be locked from re-approving after the approval (see figure 25). Which level finally locks a run is configurable. The administrator assigns the permissions for the different approval levels to the users.

### Preconfigured approval comments

The ChemStation Plus Security Pack provides the ability to globally define approval comments. These comments consist of two components - a short fixed text that cannot be modified nor deleted by the signer and a pre-defined default text that can be changed during the signing. These two components appear during the approval. The signer has to choose a fixed comment from the dropdown list box containing the pre-configured comments as shown in figure 23 and can optionally enter

or change the free-text comment. The approval comments are defined by the administrator in the global approval configuration template.

All other sensitive actions (for example, changing run-related custom field values such as the batch ID) and the archival or deletion of runs follow the same process as described above and are tied to distinct user permissions. All electronic signatures are noted

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implemented to periodically check and revise passwords, and apply the company's password policy (figure 25). The administrator can specify the values for these conditions.

- Minimum length is the minimum acceptable length (in characters) of a password. Passwords shorter than the minimum length are invalid and rejected by ChemStore C/S. The default is eight characters with a valid range between 0 and 30.
- Password expiry date is the number of days over which the password remains valid. The password expires after the specified validity, and a new password must be provided. The default is 90 days with a

valid range between 1 and 32000.

- Password uniqueness is the minimum number of new, unique passwords that a user must use before a password can be re-used. The default is 12, which means that a user must change the password at least 12 times before re-using the original password. The range is between 0 and 32000.
- Account lockout after 'x' attempts (where 'x' is the number of failed log-on attempts) is the maximum number of consecutive unsuccessful attempts that a user can enter before ChemStore rejects the password. The default is three with a valid range between 0 and 32000. If the maximum number of entries is reached, the current user is invalidated and must be reactivated by a user with the required permission.

Password settings		
Minimum password length	8	characters
Password expires in	90	days
Password uniqueness: Remember	12	passwords
Account lock out after	4	attempts
<input type="button" value="OK"/> <input type="button" value="Cancel"/> <input type="button" value="Help"/>		

**Figure 25**  
Password policy

# ChemStation Plus Security Pack — Audit-trails and change documentation

The Agilent ChemStation Plus Security Pack includes four audit-trails:

- run logbooks,
- method revision history data,
- sample audit-trail, and
- database logbook.

## Run and sequence logbook

During data acquisition, all events are documented in the sequence and run logbooks with date and time stamp (figure 26). The sequence and run logbook documents all data acquisition events such as

- start and execution of methods
- the actual sequence
- sequence table,
- any failure during execution, and
- any modification of parameters during run time
- initialization of the ChemStore

- all run versions,
- all user comments during reanalysis cycles, and
- a detailed change documentation of manual integration events.
- all approval events including the name of the approver, date & timestamp, approval comment and the level of approval.

All reanalysis events and result versions are documented in the sample audit-trail. The sample audit-trail creates for each result change one new line in the audit-trail table. It displays both the interactive manual changes and the system generated entries each in a separate line. Examples for

Sequence	Method	Timestamp
Sequence	BATCH S completed	17:41:58 06/08/00
ChemStore	Data spooled to 'lpcsc'	17:41:57 06/08/00
Method	Method completed	17:41:57 06/08/00
CP Macro	Analyzing redata 007-0101.D	17:41:43 06/08/00
Method	Method started: Line# 5 vial# 7 inj# 1	17:41:43 06/08/00
ChemStore	Data spooled to 'lpcsc'	17:41:41 06/08/00
Method	Method completed	17:41:41 06/08/00
CP Macro	Analyzing redata 006-0101.D	17:41:27 06/08/00
Method	Method started: Line# 4 vial# 6 inj# 1	17:41:27 06/08/00
ChemStore	Data spooled to 'lpcsc'	17:41:26 06/08/00
Method	Method completed	17:41:25 06/08/00
CP Macro	Analyzing redata 005-0101.D	17:41:13 06/08/00
Method	Method started: Line# 3 vial# 5 inj# 1	17:41:12 06/08/00
ChemStore	Data spooled to 'lpcsc'	17:41:11 06/08/00
Method	Method completed	17:41:11 06/08/00
CP Macro	Recalibration done	17:40:55 06/08/00
CP Macro	Analyzing redata 005-0102.D	17:40:52 06/08/00
Method	Method started: Line# 2 vial# 5 inj# 1	17:40:52 06/08/00
Method	Method completed	17:40:50 06/08/00
CP Macro	Data not available. Data Analysis not done	17:40:50 06/08/00

Figure 26

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Change Information	
Update to Enhanced Integrator	
report to file test	
no report output	
signal B and C on	
separated signals	
changed integration events	
Added method comment	

## Method changes

The method changes are stored with each current method version including a mandatory user comment for the change (figure 27). The method audit-trail stores

- the time of change and the operator who performed the change
- the current method revision in the database, and
- a mandatory comment of at least five characters each time the method was changed.

## Sample audit trail

The sample-related audit-trail, shown in figure 28 documents

- all changes and modifications, on one sample,

Version	Reason for entry	Status	Modified by	Modified at	Processed
+	New	Approval Pending	Administrator	3/15/2002 16:42:31	3/15/2002 16:42:31
+	New	Approval Pending	Administrator	3/15/2002 16:42:31	3/15/2002 16:42:31
4	New	Approval Pending	Administrator	3/15/2002 16:41:53	3/15/2002 16:41:53
4	New	Approval Pending	Administrator	3/15/2002 16:41:53	3/15/2002 16:41:53
3	Loaded as part of	Approval Pending	Administrator	3/15/2002 16:41:45	3/15/2002 16:41:45
3	Added to Batch	Approval Pending	Administrator		
3	New	Approval Pending	Administrator		
2	New	Approval Pending	operator2		
2	New	Approval Pending	operator2		
1	New	Approval Pending	operator1		
1	New	Approval Pending	operator1		

In No.	test
1	0.0000
2	2.0000
3	3.0000

**Manual Integration Details**

Start of compare 3/15/2002 5:37:46 PM  
Operator : admin  
Datafile : 005-0102.D

Compare of Signal DAD1 A, Sig=254.4 Ref=550.100

Area Difference in Peak: 1.02 min. Last value was -0.7 %  
Amount Difference in Compound: 1.02 min. Last value was 0.092591 Current value is 0.091528

Modified data have been set as reference. ChemStore is updated

List of integration events history for signal DAD1 A, Sig=254.4 Ref=550.100

Event No. 1  
Time Start : 0.942071 min.  
Abs. Start : 0.116093 mAU offset from chromatogram at begin peak  
Time End : 1.191617 min.  
Abs. End : -0.000818 mAU offset from chromatogram at end peak  
Command : Draw Baseline

Figure 28

Audit-trail table with manual change documentation in the comment field

manual interactive changes are:

- change of custom field values
- manual reintegration during reanalysis,
- approval, rejection and retransfer to batch,
- reloading data to disk,
- archiving and dearchiving, and
- re-opening of read-only runs.

The automated entries in the sample audit-trail are created when

- a run is transferred to the database
- a new result version is generated
- a run is reloaded in the ChemStation batch reanalysis interface for reanalysis

### Database logbook

The database logbook (C:\Program Files\Agilent\ChemStation\bin\logbook.exe) stores all application activities such as:

- log-on/log-off events and failed logon attempts,
- archive/delete/reopen activities,
- session locks and unlocks,
- approval and rejection of runs,
- modification of custom fields and custom field values,
- changes in user administration,
- modification of user permissions,
- password resets and password clearance, and
- database migration from Access to Oracle.
- Account lockout events.

### Review of method parameters

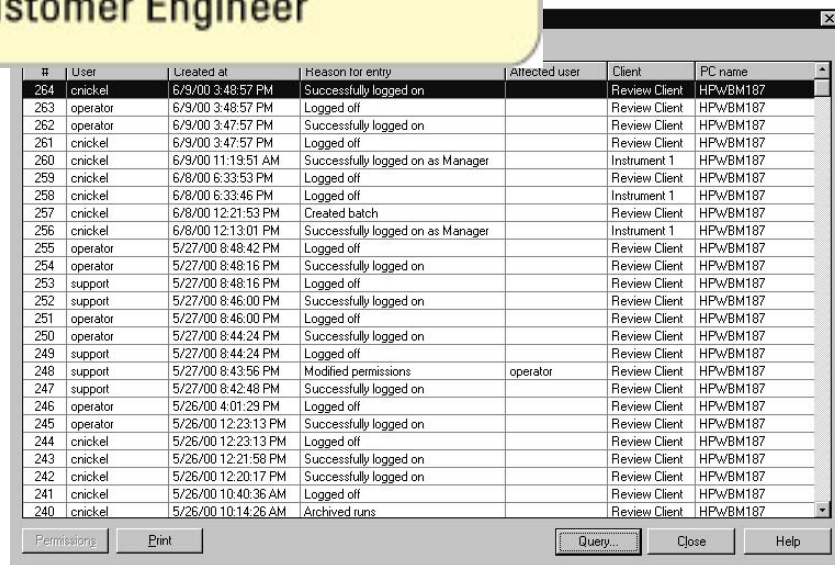
Each result version is associated with its ChemStation method that is stored in the relational ChemStore database. To inspect the differences in method parameters between result revisions or to review a method that was used to generate a specific result the application provides direct access to the method information from the ChemStore user interface. All

- the associated result version,
- method name,
- method modification date,
- study name,
- database name,
- sample name,
- injection date and
- acquisition instrument.

Changes to method parameters can only be applied in the ChemStation.

For this purpose the method has been stored from the database. Result versions generated from a modified method are stored to the database along with the method.

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#	User	Created at	Reason for entry	Affected user	Client	PC name
264	cnickel	6/9/00 3:48:57 PM	Successfully logged on		Review Client	HPWBM187
263	operator	6/9/00 3:48:57 PM	Logged off		Review Client	HPWBM187
262	operator	6/9/00 3:47:57 PM	Successfully logged on		Review Client	HPWBM187
261	cnickel	6/9/00 3:47:57 PM	Logged off		Review Client	HPWBM187
260	cnickel	6/9/00 11:19:51 AM	Successfully logged on as Manager		Instrument 1	HPWBM187
259	cnickel	6/8/00 6:33:53 PM	Logged off		Review Client	HPWBM187
258	cnickel	6/8/00 6:33:46 PM	Logged off		Instrument 1	HPWBM187
257	cnickel	6/8/00 12:21:53 PM	Created batch		Review Client	HPWBM187
256	cnickel	6/8/00 12:13:01 PM	Successfully logged on as Manager		Instrument 1	HPWBM187
255	operator	5/27/00 8:48:42 PM	Logged off		Review Client	HPWBM187
254	operator	5/27/00 8:48:16 PM	Successfully logged on		Review Client	HPWBM187
253	support	5/27/00 8:48:16 PM	Logged off		Review Client	HPWBM187
252	support	5/27/00 8:46:00 PM	Successfully logged on		Review Client	HPWBM187
251	operator	5/27/00 8:46:00 PM	Logged off		Review Client	HPWBM187
250	operator	5/27/00 8:44:24 PM	Successfully logged on		Review Client	HPWBM187
249	support	5/27/00 8:44:24 PM	Logged off		Review Client	HPWBM187
248	support	5/27/00 8:43:56 PM	Modified permissions	operator	Review Client	HPWBM187
247	support	5/27/00 8:42:48 PM	Successfully logged on		Review Client	HPWBM187
246	operator	5/26/00 4:01:29 PM	Logged off		Review Client	HPWBM187
245	operator	5/26/00 12:23:13 PM	Successfully logged on		Review Client	HPWBM187
244	cnickel	5/26/00 12:23:13 PM	Logged off		Review Client	HPWBM187
243	cnickel	5/26/00 12:21:58 PM	Successfully logged on		Review Client	HPWBM187
242	cnickel	5/26/00 12:20:17 PM	Successfully logged on		Review Client	HPWBM187
241	cnickel	5/26/00 10:40:36 AM	Logged off		Review Client	HPWBM187
240	cnickel	5/26/00 10:14:26 AM	Archived runs		Review Client	HPWBM187

**Figure 29**  
Database logbook

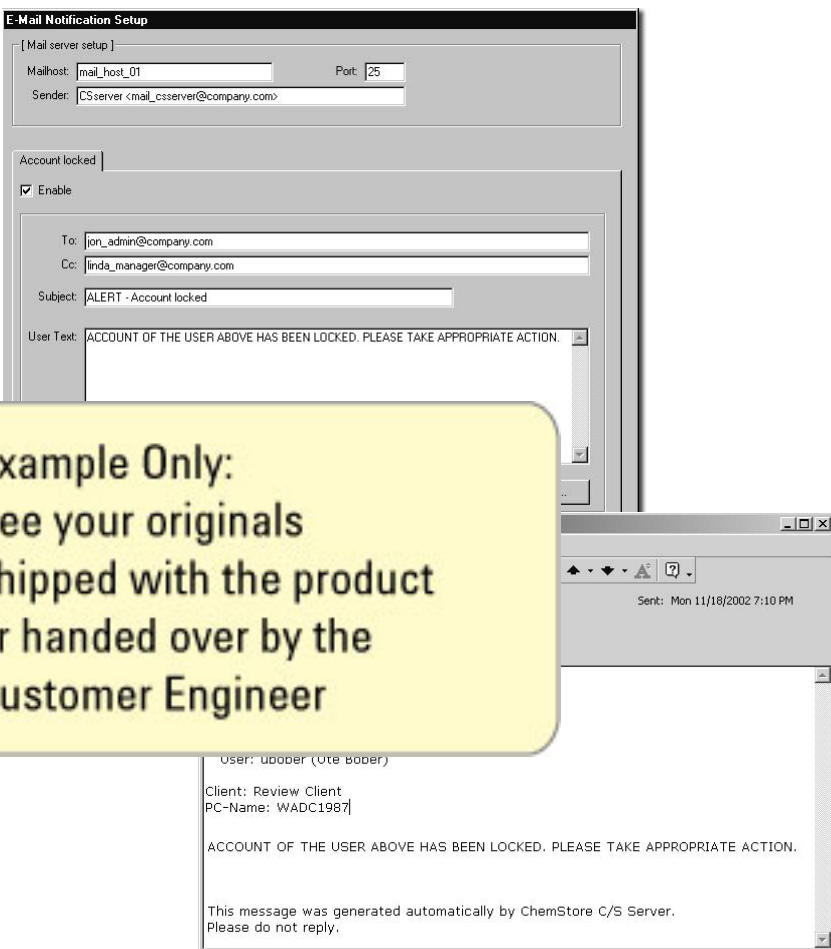
## Agilent ChemStation Plus Security Pack — E-Mail Notification

The email notification feature (client-server only) allows to send an email to a configurable list of recipients on the event of

- account lockout
- batch submission
- user permission change
- user creation

For each event the recipients can be defined separately as well as a user-defined message text and subject.

This function requires an e-mail server to be running in the network. The e-mail message can be transferred to the e-mail server using the Simple Mail Transfer Protocol (SMTP). For example this can serve for the purpose of immediate notification on unauthorized attempts to access the data. An e-mail message can be triggered by account lockout events in the ChemStore C/S database logbook. (figure 30).



**Figure 30**  
**Setup of e-mail notification**

## ChemStation Plus Security Pack—Product Options and Configuration

### Standalone version

The standalone version provides the ChemStation CD-ROM revision A.10.01 or higher and the ChemStation Plus CD-ROM revision B.03.01 or higher as described in the table next to this text.

Description	Product No.
<b>ChemStation Plus Security Pack.</b> Adds the secure ChemStore C/S relational database add-on software module to the ChemStation Plus SW for A/D, GC, CE, LC and CE/LC-MSD. Supports 21 CFR Part 11. Includes user documentation, licenses and media.	<b>G2183AA</b> 1 per PC 1 per laboratory
<b>License to use G2183AA on another PC.</b> Includes license and user information only. Supports 21 CFR Part 11. Must be on same order as G2183AA or requires a valid license for G2183AA.	<b>G2187AA</b> 1 per PC be in the same laboratory
<b>ChemStation Plus client upgrade software.</b> Upgrades a single ChemStation Plus client to the latest software revision. Requires valid software licenses and ChemStation upgrade software G1656A.	<b>G1657A</b>

### Client/server version

The client server/version product consists of a set of components that are required to implement ChemStation Security Pack in a client server version. The product number listed in the table next to this text along with the required

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	Product No.
software, d.	<b>G21410A</b> Qty: 1 per server
database.	<b>G1411A</b> Qty: (number of clients connected to server) – 5
<b>ChemStation Plus Security Pack.</b> Adds the secure ChemStore relational database add-on software module to the ChemStation Plus client server SW for A/D, GC, CE, LC and CE/LC-MSD. Supports 21 CFR Part 11.	<b>G2183AA</b> Qty: 1 per server
<b>ChemStation Plus ChemStore client license.</b> Includes one online ChemStation Plus license for online data acquisition and one ChemStore C/S offline data review license. Includes license and user information only. Requires but does not include ChemStation Plus software media.	<b>G2186BA</b> Qty: (number of clients connected to server) – 1
<b>License to use G2183AA on another PC.</b> Can be used as additional copy for standalone installations or as additional Security Pack client in ChemStation Plus Security Pack C/S installations. Includes manual, 1 license for either online or offline use and media. Supports 21 CFR Part 11 Must be on the same order as G2183AA or requires a valid license for G2183AA.	<b>G2187AA</b> 1 per PC in the same laboratory.
<b>ChemStation Plus client upgrade software.</b> Upgrades a single ChemStation Plus client to the latest software revision. Requires valid software licenses and ChemStation upgrade software G1656A.	<b>G1657A</b>
<b>ChemStation Plus server upgrade software.</b> upgrades ChemStation Plus server software to the latest revision. Includes G1656A ChemStation software upgrade. Requires valid software license.	<b>G1655BA</b>

## 4. Agilent ChemStation Plus Method Validation Pack

### Introduction

A comprehensive understanding of the functionality of Agilent ChemStation Plus Method Validation Pack requires a brief introduction to the general aspects of method validation.

The goal of method validation is “to provide documented evidence that a specific process will consistently provide results meeting the predetermined specifications.”

This definition is taken from one of the FDA's method validation guidance documents. In order, method validation is the process of evaluating and documenting the performance of an analytical method to ensure that the method is suitable for its intended use, ensuring compliance with regulatory requirements. The outcome should provide confidence in the results obtained with a particular method.

The analytical purpose of the method validation experiments is to provide a master method with a master chromatogram for all consecutive separations of this particular sample. Method validation testing must compare results of multiple runs (it is inter-chromatographic) in order to answer the question “is this method suitable for the separation task?” The comparison must give a qualitative and quantitative answer to this question based on the analytical results. A comparison typically involves a human judgement, so how can a comparison provide a user-independent and quantitative result? This is the most difficult task in the method validation process, because proper execution requires:

1. The definition of general good quality criteria for a method to address the qualitative requirements, and
  2. The definition of specific requirements for the individual analytical problem to address the quantitative question.
- Eventually it requires an answer to the question “does this method provide good results based on independent requirements?”

For step 1, ICH and FDA used the definition of general good quality

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- linearity
- calibration function

Based on the compound type, all or a subset of these criteria must be met. Most common compound types are

- main compound
- side compound
- known impurities
- unknown impurities

It is obvious that it is not necessary to determine the limit of detection for the main compound as the amount of the main compound will always be closer to saturation than to limit of detection. A detailed list of compound types and appropriate test criteria can be found in ICH and USP literature. Method Validation Pack uses built-in templates to automatically

configure the method validation according to the guideline under consideration. The ICH has also published a guidance on “Stability Testing in New Drug Substances and Products” to define the required amount of information and procedures for the submittal in a registration application for products (ICH Topic Q1A). The purpose of stability testing is to provide evidence on how the quality of a substance varies with time under the influence of a variety of environmental factors such as temperature, humidity, and to establish a re-test interval for the substance, and extended storage conditions. Method Validation Pack does tests for short-term and long-term stability testing according to ICH guideline.

Based on these test criteria, step 2 is executed. This is an individual definition of requirements (quantitative limits) for the statistical results of the tests by the responsible validation person. This step must be repeated for each new validation and will require different limits for each validation experiment. Method Validation Pack maps this step with a set of advanced statistical calculations. The calculations offer simple summary statistics (RSD, %RSD and linear regression statistics) as well as a set of advanced calculations for outlier detection, trend tests and many more. For each criterion, a different set of statistical calculations on the result values is performed based on the test requirement. The administrative user defines the calculation limits, transferring analytical requirements into

quantitative result criteria. Method Validation Pack offers tests such as Neumann trend tests and Outlier tests (e.g. according to Dixon) and many more to provide and document an assessment of the quality of analytical separations.

Method validation is an iterative process. Through the course of the validation it might turn out that some acceptance criteria need to be revised or even that the whole method of analysis is not suitable for solving the analytical problem.

To support this approach the Validation Pack allows to create and manage multiple versions of the same validation.

Step 3 is to construct the validation report including validation data, results, statistics, graphics and other information such as record of standard operating procedure, sampling, analysis etc. Method Validation Pack includes a variety of different reporting functions.

## What's New?

With the latest revision users can benefit from new functionality in many areas as listed below.

### Validation planning

- Solution stability calculations for short-term as well as long-term stability studies (see *ChemStation Method Validation Pack — Checkpoint Planning* on page 52)
- Enhanced handling of selectivity data and calculation (see *ChemStation Method Validation Pack — Checkpoint Planning* on page 57)

### Validation execution

- Submission of custom validation sequences (see *Working with ChemStation Plus Method*

*Validation Pack — Level 3: Checkpoint planning* on page 49)

- Partial execution of validation sequences (see *ChemStation Plus Method Validation Pack — Interaction with other ChemStation Plus modules* on page 58)

### Validation report

- Calculation formula documented in the report
- One-page summary report
- Optionally color-coded test results in the reports

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or handed over by the  
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- Export of validation reports in pdf-Format (see *ChemStation Plus Method Validation Pack — Data Security* on page 62)

### Administration

- Unlocking of locked validations with an electronic signature (see *ChemStation Plus Method Validation Pack — Data Security* on page 65)

### User documentation

- Revised Method Validation Pack User's Guide and Online Help

## Product description

Agilent ChemStation Plus Method Validation Pack is a data management system for all method validation data. It includes advanced statistical calculations and result management in a relational database. Method Validation Pack offers a compound-centric design. For each

compound it allows to define a set of tests (checkpoints) according to ICH, Pharmacopoeia or DIN guidelines. By default each test requires results of at least six repetitive injections in order to use statistics for a quantitative result evaluation. In some areas less than six values can be used, but then some statistical evaluation methods are omitted. The statistical results can visualize whether the analytical results meet their specifications or show any deviation. When all tests passed, the compound meets the requirements. When all compounds meet the requirements the method is seen as applicable or "validated" according to its well-defined procedure and with the specified acceptance criteria. At this stage, the validation is locked, the full validation is documented and the validation study for the method can be archived.

Validation Pack provides all required statistical functions and calculations, stores all results with their raw and meta data, displays the statistical results graphically, and captures all actions in automatic user-independent audit-trails. Further, it allows to map the key steps in validation experiments - planning and definition of expected results, experiment execution and result evaluation - as separate tasks tied to different user permissions. All steps are documented in audit-trails and are fully traceable. Method Validation Pack is equipped with a fully featured document management system (DMS), that is used to retain and manage all versions of a validation (including all attachments). The DMS provides a powerful search engine, further complemented by the ability to tag validations with additional keywords.

## Agilent ChemStation Plus Method Validation Pack — Work Flow

### Configuration

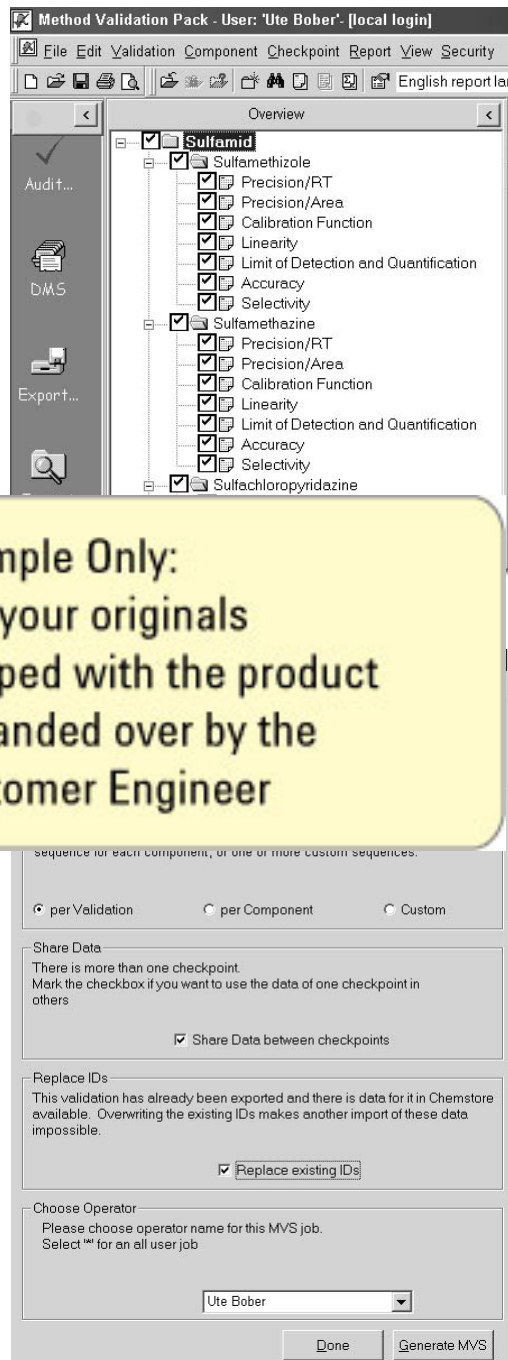
The configuration of validation experiments is hierarchical (figure 31). The top level represents the complete validation experiment. This level may include standard operating procedures (SOP) for sampling, sample preparation, description of quality and grades of solvents, testing materials, a description of the analytical method and so on. Such information can be directly added as validation comments or enclosed as document attachments to the validation.

The next level introduces compound-centric validation in the form of components. This enables individual calculations and validations for each compound or peak in an analytical separation by structuring the validation according to the components possible to define method elements for the same compound (for example if matrix effects are investigated).

For each component, additional sub-levels offer a list of checkpoints such as robustness, linearity and others as defined in the various regulatory guidelines. The planning of checkpoints is the lowest level because each checkpoint can have a different planning configuration. Within the planning dialog, data is configured such as the determination method, the applicability of multiple injections, or multiple determinations for one result data point as well as the number of result values and test specifications such as nominal (expected) values or limits.

### Test execution

Having completed the validation configuration, the experiments can be executed on an Agilent



**Figure 32**  
**Options for generation of Method Validation sequence**

ChemStation Plus system. Method Validation Pack transfers the theoretical validation planning into a list of analytical runs by creating one or multiple ChemStation

method validation sequences (MVS). The user has three options during sequence generation. As shown in figure 32 the validation

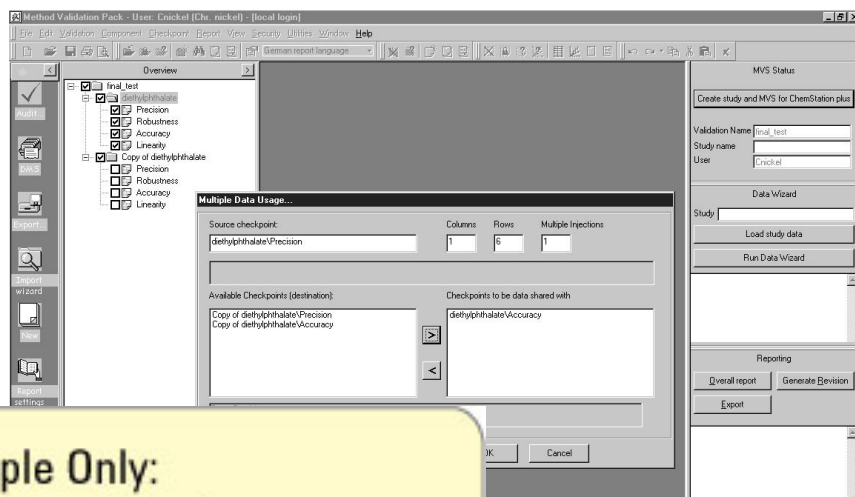
can be transferred into

- a single sequence for the complete validation
- one sequence per component
- or a set of user-defined custom sequences.

The custom sequence option allows to define as many sequences as required in any combination of the individual checkpoints. During the submission the sequence can be assigned to a specific owner or made available to all users.

To minimize the amount of unnecessary data and to make some checkpoints optional, the same function can be used. This function can be used for the MVS export option. For the ease of use, the Method Validation Pack proposes which checkpoints are suitable for sharing and which should not be shared.

For the ease of use, the Method Validation Pack proposes which checkpoints are suitable for sharing and which should not be shared. The results of the method validation sequences are stored automatically in the ChemStore database. Each validation corresponds to a separate ChemStore study. If a validation sequence failed it can be resubmitted and rerun. Or if only parts of a validation sequence need to be repeated, for example



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accordingly.

### Result data entry and statistical calculations

After completion of the analytical experiments the results can be uploaded from the ChemStore database into Method Validation Pack. The upload from ChemStore is an automated direct database data access invoked by the user. The transfer is executed as defined in the planning of the validation experiments. The data wizard helps to find and complete data sections, that require manual entries. The analytical results are contained in the ChemStore data-

whereas the validation results are contained in Method Validation Pack. Traceability of results is

achieved with unique run-IDs in ChemStore for each result version. The ChemStore run-IDs are also transferred and displayed along with the analytical results in the Method Validation Pack.

When all result data is imported, the validation report can be printed. This report displays all data related to the validation as defined in the top-level validation configuration. This includes the components, their planning and result data as well as the calculation results, statistical data and conclusions, for example, "outliers [not] detected" along with a graphical representation of the results in charts.

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## Data management and audit-trails

All configuration and result data along with the MVS files and validation reports form the “validation”. It is stored in a relational database for full data integrity and to ensure data security. Every validation modification or configuration change is stored in the DMS

database as a new version of the existing validation. All changes and modifications are documented either in the program audit-trail (for program related events such as logon) or in the validation audit-trail. In a server-based installation all validation data is stored in additional Oracle tables of the same database instance as used by the ChemStore database. In the

entry-level system each validation is stored in a separate validation database on the local hard disk (file extension .VDB).

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## ChemStation I

### Compatibility with ChemStation Plus

Agilent ChemStation Plus Method Validation Pack A.02.01 is compatible with the following ChemStation Plus modules:

- Agilent ChemStation for GC, LC, A/D, CE, CE/MS and LC/MS for instrument control and data analysis
- Agilent ChemAccess remote access and module
- Agilent ChemStore data organization and data storage module

For result management in a relational database, Method Validation Pack requires the ChemStore database or ChemStation Plus Security

application. The standalone database file format adheres to a common standard, which is used by many other applications, for example, MS Access. The client-server version is based on an Oracle relational database.

### Hardware requirements

The following list shows the minimum hardware requirements for the client application:

- 600-MHz Pentium III (Pentium IV recommend)
- 4 GByte of free hard disk space

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## nts

128 MB RAM for single ChemStation instrument. 256 MB is recommended for best performance, for Windows XP the minimum requirement is 256 MB.

- 256 MB RAM for two ChemStation instruments (512 MB or more is recommended for best performance)
- Display: 1024 × 768, small fonts, 65-thousand colors

Method Validation Pack installs and runs on the same instance of the Oracle database as ChemStore C/S and thus does not require a separate Oracle licence. For server hardware requirements, please refer to the server hardware requirements

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for ChemStore on page 5.

### Software requirements

- Windows 2000 Professional with Service Pack 4 or Windows XP Professional Service Pack 1a
- Agilent ChemStation revision A.10.01 or later
- Agilent ChemStore C/S B.03.01 or higher
- Microsoft Internet Explorer 5.5 or later
- Microsoft data access components (MDAC) 2.8 will be installed on your system. If you already use a later version of MDAC, or require compatibility reasons a previous version, please contact your support representative for compatibility information.
- A printer must be configured in Windows.
- The hard disk partition that is used for installing Method Validation Pack must be formatted with

paragraph.

### Client-server installation

The client-server version of Method Validation Pack is based on an Oracle relational database. The application supplies three pre-defined schemes for the database installation: small, medium and large. The databases are separated into multiple tablespaces for better performance and administration. In particular, the tables storing the validation data (comments can contain large graphics) and those reserved for

versions; changes to one VDB file are stored as a new version, new VDB files create a new entry in the DMS system. The required space for an individual VDB file was discussed in the previous section.

Database parameter have been chosen for unattended operation; tablespaces and datafiles extend automatically until their maximum file size has been reached. Nevertheless, you should keep in mind that frequent database maintenance and administration is

necessary to ensure optimum performance and correct and reliable operation (backup tasks, checks etc.). Your database administrator may manually expand your database if necessary. There is no known database size limitation in Method Validation Pack.

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### Hard disk space

#### Standalone installation

Method Validation Pack needs approximately 40 MB hard disk space for the installation files. The validation database files (VDB) typically require 250–1000 KB each. The exact size strongly depends on the size of embedded graphics. If possible, use vector graphics (WMF-format) rather than bitmap graphics (BMP) to reduce the validation file size. Using large bitmap graphics in validation comments also has an impact on the DMS size. Hard disk requirements for the Oracle database are discussed in the following

Large						
VDB data	Database	MB	Database	MB	Database	MB
	Initial size	30	Initial size	600	Initial size	1200
	Maximal size	300	Maximal size	1200	Maximal size	2400
	File growth	15	File growth	30	File growth	60
	Comments		Comments		Comments	
	Initial size	100	Initial size	1400	Initial size	2800
	Maximal size	700	Maximal size	2800	Maximal size	5600
	File growth	40	File growth	70	File growth	140
DMS data	Database	MB	Database	MB	Database	MB
	Initial size	20	Initial size	500	Initial size	2000
	Maximal size	200	Maximal size	1000	Maximal size	4000
	File growth	5	File growth	25	File growth	100
	BLOBS		BLOBS		BLOBS	
	Initial size	180	Initial size	4500	Initial size	18000
	Maximal size	1800	Maximal size	9000	Maximal size	36000
	File growth	45	File growth	225	File growth	900

**Table 13**  
Preconfigured database sizes for Method Validation Pack in a client-server configuration using an Oracle relational database

# Working with ChemStation Plus Method Validation Pack

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## General software operation

### Compatibility with Microsoft functionality

Method Validation Pack is a Microsoft Windows program and can be operated via mouse and keyboard in accordance with the Microsoft Windows standard. Users of Microsoft Windows programs should easily become familiar with operating Method Validation Pack.

### Context menu

When working with Method Validation Pack, the right mouse button opens the context menu displaying your current options. The context menu consists of functions connected to a selected component, components, or attributes of a graphic object. All functions of the context menu are also accessible via the menu bar.

### User interface setting

All settings that are changed in the menus or tool bars are recorded for the user and saved at the end of a session. They are automatically loaded during the users next login.

### Navigation bar

On the left side of the screen, the navigation bar presents the most important top-level functions of Method Validation Pack. You can use this bar for directly selecting the

- program, default validation or current validation audit
- Document Management System (DMS),
- export dialog,
- import wizard for templates,
- new validation wizard,
- planning wizard,

- report settings (output formats, etc.), and
- security settings

### Ease of operation

All important tasks in Method Validation Pack are accompanied by wizards to make it easier for the novice user to become familiar with the main tasks.

### Validation assistant

Method Validation Pack comes with an additional validation assistant that helps to configure and setup Method Validation Pack functionality. An administrator can configure

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- Opening an existing validation
- Opening the last Validation (per user)

The validation assistant guides the user through all configuration and planning steps in Method Validation Pack. It can be used either to create a new validation or to add a new component to an existing validation. It is accessible from the validation or help menu or via the context as described earlier.

### Data completion wizard

Some checkpoint information (such as the concentrations for linearity) can only be added after data acquisition. It is not available during checkpoint planning. Method Validation Pack therefore

has an integrated data completion wizard. As long as a checkpoint is not complete, the related report cannot be generated and is flagged incomplete with an invalid-data entry in the table of contents. The Data Wizard points the user to all incomplete checkpoints prompting him for completion. Double-clicking it opens the data input grids. Input fields with a dark background are locked and supposed to be automatically populated with data from the ChemStore study. Input fields with normal background color require manual entries.

### Validation structure

ChemStation Plus Method Validation Pack translates the user requirements into a defined workflow following a structured approach to analytical validation. It requires the user to thoroughly configure and validate before executing an analytical experiment. By design it forces the user to separate method validation testing into three steps:

- planning and design,
- test execution (run samples), and
- result calculation based on the experimental result data.

All of these tasks are managed within ChemStation Plus. All ChemStation Plus modules support data security, data integrity and audit-trails for comprehensive support of FDA's requirements for electronic records and electronic signatures (21 CFR Part 11). The combination of audit-trails in all ChemStation Plus modules with the advanced data security features built into the relational database offers full traceability and complete documentation of all steps during the method validation experiments.

## Method Validation Pack hierarchy

The Method Validation Pack software structure is strictly hierarchical, divided into five levels. These levels also correspond to user-access levels. The list below outlines the step-by-step execution of the method validation experiments with the hierarchical structure and the user access levels.

### Before acquisition – validation template

- 1) **Setup and configuration (User levels 5 and 4)**  
Overall validation method definition of program and component configuration in the Method Validation software

- Automatic translation of the validation into one or more system-generated ChemStation sequences based on the validation configuration and
- Submission of the sequence(s) to the ChemStation for data acquisition

### After acquisition – the validation report

#### 4) Data completion and results

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#### 5) Creating the method validation report (User level 1)

- After data completion, the method validation report is compiled according to the report configuration in step 1 (style and level of detail, for example charts, statistical details, calculation formula)

Figure 34 again illustrates the steps described above. All configuration transfer steps are fully automated and integrated with the ChemStation Plus modules. Data transfers are automatically documented in audit trails thus preventing any accidental transfer or description error.

### 2) Checkpoint planning (User level 3)

Each checkpoint can use different calculation methods depending on the applied guidelines. The checkpoint configuration step is either repeated for each checkpoint or it is copied from another component using drag and drop functionality.

### Data acquisition – the validation experiment

#### 3) Experiment preparation, data management and execution (User level 3)

This step consists of:

- Creation of new or update of existing ChemStore study for the analytical result data

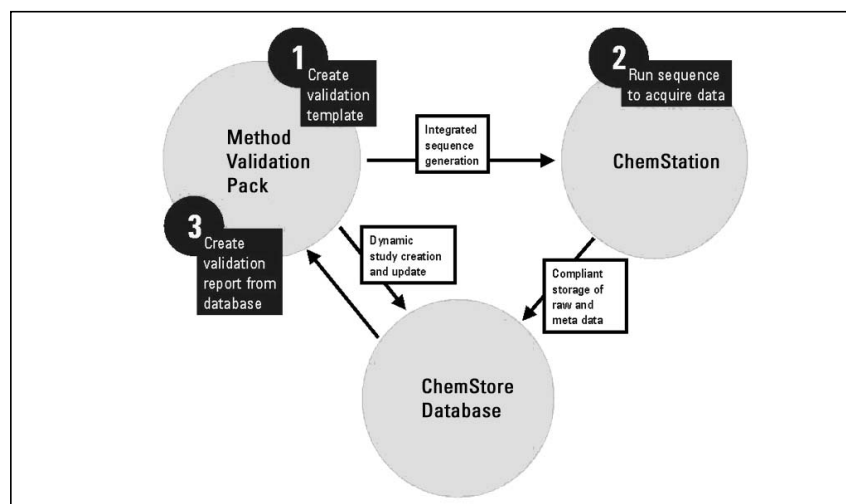


Figure 34  
Interaction of ChemStation Plus software modules and their mapping of the key steps of method validation experiments

## User levels

### Top-level (Level 4 and 5): Validation setup and configuration

#### Setup

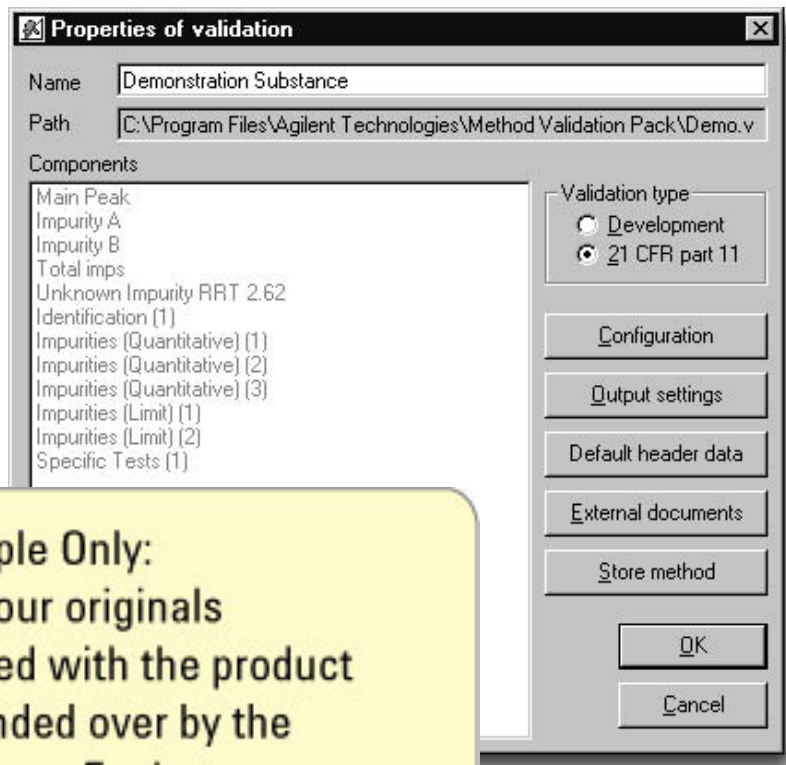
Method Validation Pack organizes data in method validation databases. A method validation database is the top-level container for all data that relate to one validation. All settings are linked to one validation database. For new validations the software offers a master validation

template that allows for multiple validations based on the template. The following settings are configured per validation (figure 35) and can be changed in a template:

- validation configuration
- output settings,
- default reporting
- storage of external documents and,
- storage of method in text format.

#### Validation configuration

The validation configuration defines the parameters for the statistical calculations in the report. Each checkpoint offers different calculation options and is configured individually. For example the user may decide which level of significance should be applied for the t-values for the t-test as part of the selectivity checkpoint (default is “5% two-sided”). In addition, the configuration task defines overall calculations that are common for all checkpoints. These include outlier tests, trend test, homogeneity tests and systematic error detection. Other settings allow specifying the minimum sample size for each test, handling of zero as input value and handling of missing values.



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up and configuration

For non-Part 11 validations (“development validation”), the user may also specify the audit-level in the configuration.

#### Output settings

The method validation output settings define the output format and content of the validation report. For each checkpoint the extent of statistical information contained in the report can be configured separately. For details on the checkpoint content, please see the checkpoint section later on. Further, output settings define the decimal precision for the result data shown in the report as well as graphic settings, text elements, and whether or not to document the configuration values in the report or include audit trail information.

For text elements the output settings define:

- the report title page,
- an additional general report comment page,
- the report header
- additional footer text, and
- default comments for validation planning and validation configuration

In addition, the text configuration defines the checkpoint table headers. Each checkpoint can have up to ten freely configurable header data items with different user-defined content. The header information is used to describe general validation information that is necessary to uniquely identify and characterize the method validation experiment. Examples for useful

table header are the product name, the analytical equipment, QS or internal ID number, test method and others. Default entries for the header data can be defined when selecting the default header data button in the validation properties. Figure 36 shows table headers and default header data.

Product	Test method	Test criterion	X-Dimension	Meas. sys.	QS-Number	Device type	Device-No.	Comment
Wonderdrug	W/DG_rev.4.1	run number	HPLC with MSD	ABX_230666	Agilent 1100 series	System 3	No comment	

**Figure 36**  
Default headers (grey) and header data

Table headers can only be changed or overwritten by changing the complete validation configuration while the default header data can be overwritten for every checkpoint.

The graphics section defines the checkpoints that will have graphic result visualization in the final report.

**Default (checkpoint) header data**  
This section defines the header data section of the checkpoint report as defined in the output settings. It provides a single entry point for common data for all checkpoints e.g. the method name or an internal code for the tests. All data that are entered as default reporting header data are copied to all checkpoint headers. The default checkpoint header data can be manually modified for each

individual checkpoint if the actual information are different from the preconfigured header data. Using default header data speeds up the checkpoint configuration as it allows skipping multiple data entries for the checkpoint headers. One example that might outline the usage of default data for the

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data to all checkpoints. For the ruggedness checkpoint the default header data for the instrument will be manually overwritten, for all other checkpoints the default header data are copied and do not need a manual entry.

**Storage of external documents**  
Users can store any external document with the validation. The document must be available as a file with an extension that allows direct read-out and data display. This is particularly useful for adding master methods, sample preparation and other method related information to the validation. During printing all external documents can be integrated into the final validation report. The storage capability of external documents in the method validation database allows using the Method Validation Pack software as a container for all method validation related data (see also the section on the DMS on page 62).

#### Store method

Store method allows adding the method as a text file to the validation database. The method must be in file format and can not be a folder or anything else that can not be opened with a standard editor.

#### Component configuration Checkpoint configuration

level under the top-level component level. The component typically relates to a compound (or in ChemStation to a compound) in a component but it allows having multiple components for one peak to perform result comparison or result copies. Usage of multiple components per peak is mainly used during method development. During component configuration the user may specify a unique name for the component along with the checkpoints that will be executed for this component. Checkpoints are either created according to a user selection or can be based on predefined templates. The templates include:

- Complete range (all checkpoints will be selected),
- Trace method (selecting precision, calibration function and limit of detection/quantification),
- Trace method with demand (above plus lab capability)
- Non-trace method (precision only), and
- Non-trace method with demand (above plus lab capability)

Each component typically includes one or multiple checkpoints from the following list:

- Precision - used to monitor random errors
- Robustness/Ruggedness
- Lab capability (mainly used in non-pharmaceutical applications)
- Calibration function
- Limit of detection/quantification
- Accuracy
- Selectivity
- Ring experiment (used to compare results among multiple laboratories)
- Linearity

The checkpoint configuration will typically depend on the compound type, and hardly any requires execution checkpoints. The system requires running the configuration for each individually.

### Level 3: Checkpoint

Each checkpoint requires a method. The configuration includes the test and calculation methods, data sources and data types for x- and y values (e.g. for linearity x-value is amount in mg/mL and the y-value is peak height). A typical planning dialog, in this case for accuracy is shown in figure 37. The following sections are configurable for all checkpoints:

- **Headers**

These data sections will show the default data if configured in the validation properties and allow individual data entry for each header line

- **Planning data**

Selects the calculation method from a pool of possible calculations available for this checkpoint

- **Number of samples and y-unit**

Defines the number of independent samples used for calculations (*Note:* By default, minimum number must be six and the system will show missing values either as Zero or as MV in case the configuration allows 0 as valid data input). Each sample translates into a separate sequence line and thus sample vial.

- **Multiple injections or determinations**

“Multiple injections” means repetitive injections from the

- **ChemStation Plus Method Validation Pack – Planning**

In this planning area the user configures the ChemStation result data type for the checkpoint calculations. For example for precision data the calculation can be either based on peak area or peak height as determined by the ChemStation. Additional header information can be imported from ChemStore along with the result values. Available result values are peak area, peak height, peak width, retention time, and amount.

For the selectivity checkpoint, resolution data is obtained with different calculation methods as provided by the ChemStation (tangent method according to USP/EP/ASTM, halfwidth method, sigma method, statistical method). Additional header information can be:

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The screenshot shows the 'ChemStation Plus Method Validation Pack - Planning' dialog box. It is organized into three main sections:

- Headers:** A table with the following data:
 

Product	late night wake up drug
Test method	batch
Test criterion	According to ICH
%Dimension	Run number
Meas. sys.	HPLC
QS-Number	fantasy
Device type	Agilent 1100
Device-No.	for serial numbers see checkpoint header
Comment	no comment
- Planning data:** Contains radio buttons for 'Determination method':
  - ☒ Comparison with nominal value (Nominal value  $\mu$ : 1.2)
  - ☐ Method comparison with joined sample
  - ☐ Method comparison (Nominal value CV: 0)
  - ☐ Standard addition (Number of values with matrix: 0, Addition z: 0)
  - ☐ Extended spiking method
  - ☐ Recovery
  - ☐ Accuracy by recovery (Nominal value CV: 0)
 Below these are input fields for 'Number of samples' (6) and 'Y-Units'.
- Accuracy:** A text area containing a detailed explanation of accuracy as a qualitative concept, its influence by systematic and proportional errors, and the use of t-test and Wilcoxon-Matched-Pairs-Signed-Rank-Test for comparison with nominal values.

At the bottom are 'Comment', 'OK', and 'Cancel' buttons.

**Figure 37**  
Checkpoint planning window (example for accuracy) with sections for checkpoint header data, test planning data, number of results y-units and multiple determination.

- study name,
- method name,
- method text,
- instrument name,
- instrument module with serial numbers,
- run Ids (database Ids),
- run Id with version number,
- run Ids and approval status,
- run Ids and raw data file path, and
- all custom fields with data entries.

The system allows a 5 additional header information from the database.

After the planning procedure can be translated into one ChemStation sequence. Validation Pack provides

ability to submit a sequence

- per validation,
- per component, or
- as a number of custom sequences

to the ChemStation.

When choosing to create a sequence per validation, the software generates a single sequence containing all necessary sequence lines to complete all tests in one sequence. This will be the most suitable and efficient way in case the method will not be transferred between instruments and thus no ruggedness testing is required, or if no time-consuming tests are involved such as long-term stability. If a validation is structured per component in a way that each

component can be validated in a separate sequence either on the same or a different instrument, sequences can be submitted per component. Method Validation Pack then creates a sequence for every component.

Depending on the number of compounds and the extent of validation it might be useful to define your own set of validation sequences. For this purpose the custom sequence submission

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submit the sequence. To make it transparent to the user, which checkpoints were already submitted, these are immediately highlighted in green.

The number of necessary experiments can be further reduced by the ability to share data between checkpoints, for example by using the same data set for more than one test, like for example reusing linearity data for the calibration function checkpoint. Data sharing is defined during sequence submission, where the software automatically offers all available choices that would allow data sharing due to the same data structure.

## Level 2: Data input

After checkpoint configuration and planning is completed, users can start with the data entry. This is the first step involving experimental result data and following the planning phase.

Method Validation Pack offers three types of data input:

1. Automated data upload from the ChemStore database. Users select to load study data from the ChemStore study created for the validation and all data are automatically imported as configured in the planning phase and described in the previous section. Data import for all result data that is not created by the ChemStation and managed in the ChemStore database e.g. data from non-Agilent instruments generated during ruggedness testing. The system comes with an import filter function allowing for an automated data import. For details see the separate section on data import below.
3. Manual data entry - for all data that are not created on a computer system, e.g. pH values, the system allows for a manual data entry.

### Data import

Data import uses an import assistant, which helps users to import data from external result summary files, typically in spreadsheet formats. It imports various file formats such as CSV, TXT, Microsoft Excel and any other ASCII formats.

where the file extension has to be specified if it differs from ASC or TXT. The import assistant displays a definition dialog enabling Method Validation Pack to automatically load this summary data to its data input grids. The following definitions can be made:

- name and description of the import mask,
- source type (file extension) and path,
- field separator (delimiter),
- row options,
- data positions allow to include/exclude header and data (with optional transformation of the data), and
- column information for naming, sorting and determining

The import settings can be saved as import mask and applied at any later time to import data. The system can handle multiple data import masks allowing to quickly import results from various data sources.

### Level 1: Reporting

Method Validation Pack software offers multiple reports. Users can have

- planning reports—print all data from the planning dialog,
- graphics report for each checkpoint—prints only results in graphic representation,
- complete reports on checkpoint level, component level, and
- complete validation reports with all validation settings and all component and checkpoint results.

The validation report includes the following parts:

- Page header and page footer (Footer includes printed user name, date, page # of # and a signature placeholder for manual report sign-off.)
- Report title page
- Default comment page
- Table of contents with page numbers

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explanatory text and a complete legend of the variables and symbols. This function is enabled on a global level via the report options as part of the program options.

- validation audit trail (optionally)
- a flag in the footer of the report indicating that the validation was done with a reduced level of audit trail (*development validation*, see page 47)

#### Available report styles

Method Validation Pack offers two report types:

- Normal report - standard report containing detailed information
- Short report - compact report containing only the most important sections and omitting for example statistical details

Both reports can be compiled in two different styles:

- Classic report - standard report look
- Modern report - different appearance using color-coded results (passed/fail)

Finally the software offers a concise summary report providing a one-page summary of the complete validation results. It contains only the checkpoint results and the test result (passed/fail statements).

#### Report customization

The following elements can be configured within the Method Validation Pack application:

- report language: German or English,

- report fonts and sizes,
- graphics section: line style, background color for data, color of axis and display of limits, axis annotations, and
- text sections: title page, validation comment page, report header and default planning and execution comment. All text sections can also include graphics such as company logos.

Method Validation Pack uses a Microsoft-Word-based reporting engine. If further customization is required it allows to open the entire method validation report as a MS Word document. This allows for easy data export of the complete validation report and easy modification and customization of the report document.

## ChemStation Method Validation Pack — Checkpoint Planning

This section lists all checkpoints with their planning options and a short explanation of their meaning.

### Precision

Precision describes the extent of conformity between results obtained during repeated use of a set analytical method under recurrent and comparable conditions. Monitoring the precision records random errors. Precision can be planned as precision in the true

sense, or as repeatability or reproducibility. In both cases (expected) values of the confidence interval can be entered. Precision can be used for proving long-term stability according to Q1A and Q2B. The purpose of the testing is to provide evidence how the quality of a substance varies with time under a variety of environmental

conditions, such as temperature, humidity, and light, and to establish a re-test period for the substance and recommended storage conditions. Stability according to Q1A is used for proving long-term stability, i.e. that an analytical substance is stable within a given range, normally for a period of 12-35 months. To do so, a linear regression is calculated and the extrapolated regression values as well as the extrapolated values of the confidence interval are compared against the acceptance period. Stability according to Q2B is used for proving short-term stability, i.e. stability of the analytical substance (typically 24-48 hours). In both cases the study duration, the initial value (initial amount or response of a freshly prepared standard) and the specification limit in percent (acceptance

interval) are entered. For long-term stability a minimum storage duration as acceptance period is additionally specified. Precision can be performed with multiple injections as well as multiple determinations. Figure 38 shows the planning dialog for checkpoint "precision".

#### Planning data

- Determination method:
  - Precision

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- Confidence interval

- Error of result
- Trend test according to Neumann
- Outlier test according to Dixon/Grubbs
- Normality check (Shapiro-Wilk-Test)
- Method standard deviation
- Mean value
- Correlation coefficient

### Robustness/Ruggedness

Robustness is defined as the independence of an analytical result from changes in other parameters, which could influence the result. The ruggedness of an analytical method is given if the deviation of laboratory mean values is not significantly different from the deviation of all measured values. Ruggedness should show the stability of an analysis with respect to the influence of transferring a method to another

The screenshot shows the 'Precision' planning dialog in ChemStation Plus Method Validation Pack. It includes sections for Headers, Test data, and Precision. The Headers section contains fields for Product, Test method, Test criterion, X-Units, Meas. sys., QS-Number, Device type, Device-No., and Comment. The Test data section includes radio buttons for Precision, System precision from linearity, and Stability test, along with fields for ICH Q1A, Study duration, Initial value (standard), Specification Value (in %), and Minimum storage duration. The Precision section includes fields for Number of values, Y-Units, Multiple determination, and Number per value. The Precision section also contains a list of calculated parameters: Precision, Repeatability conditions, and Reproducibility conditions.

Figure 38  
Planning dialog for checkpoint "Precision"

instrument. Sometimes both terms, robustness and ruggedness, are used interchangeable. Whether or not a method is considered as robust/rugged is distinguished by the fact that a change of parameters (method setpoints, environmental conditions, instrument etc.) within a reasonable range has no significant influence on the result. The F-test and the t-test can be applied as statistical criteria for the evaluation. As a measure for ruggedness, the comparative standard deviation is calculated. Figure 39 shows the planning dialog of the checkpoint “ruggedness/robustness”.

#### Planning data

- Determination method
  - Comparison of results
  - Comparison with reference
- Other data:
  - Number of series (from 2-50)
  - Y-units
  - Multiple injections possible
  - Nominal value for the standard deviation

#### Output settings for calculations

- Comparison of results
- Neumann trend test
- Dixon or Grubbs test for outliers
- Variance homogeneity
- Repeatability limit
- Reproducibility limit
- Error of result
- Range of confidence (repeatability conditions)
- Range of confidence (reproducibility conditions)
- Test for robustness
- Comparison with reference
  - Apply t-test
  - Apply F-test

**Robustness**

ChemStation Plus Method Validation Pack - Planning

Data type: Height

Additional header info:

Header line 1:

Header line 2:

Header line 3:

Header line 4:

Header line 5:

**Ruggedness**

- **Result-comparison:** Ruggedness is defined as the independence of an analytical result from changes in other parameters, which could influence the result. Ruggedness is given if the spread of the lab mean values has no significant influence on the total spread of all measured values.
- **Comparison to a reference:** Here the ruggedness is determined with the help of t-test, F-test and the nominal standard deviation (typically the result of the ruggedness test).

**Lab Capability**

- Lab capability is concerned with the relationship between the dispersion of values caused by the measuring process and the requirement, such as specification. Lab capability occupies a special position among validation concepts because it does not exclusively refer to the analytical method.

**Planning data**

Determination method:

☒ Comparison of results

☐ Comparison with reference

Nominal value  $\sigma$ :

Number of series:

Y-Units:

Series:

Series	Number of values
1	6
2	6

**Sample data**

Sample	Number of values
1	6

Lower specification:

Upper Specification:

☐ Calculate  $\Sigma b$   $\Sigma b$ :

☐ Same number of values per row

Multiple determination:

☐ Multiple injection

Number per value:

☐ Multiple determination

Number per value:

Comment:

OK Cancel

**Figure 40**  
Planning dialog of checkpoint “Lab Capability”

The following results are always calculated for robustness/ruggedness testing:

- standard statistics such as mean value, RSD, repeatability and reproducibility along with confidence intervals for repeatability and reproducibility, and
- variance homogeneity according to Bartlett.

### Lab capability

Knowledge of lab capability is necessary for accurate process capability (see parts 33 and 11). Lab capability is not required by the FDA. It checks for the ratio of dispersion versus specification. Lab capability occupies a position among Validation because it does not refer to the analytical result. Figure 40 shows the planning dialog of checkpoint "linearity".

#### Planning data

- Number of samples
- Y-units
- Lower specification
- Upper specification
- Calculation of  $X_b$ , where  $X_b$  is the reference value (expected analytical result value)
- Multiple injections possible

#### Output settings for calculations

No output settings can be configured by the user. For lab capability, the lab capability index  $C_m$  and lab performance index  $P_m$  are determined, as well as the corrected values  $C_{mk}$  and  $P_{mk}$ . The result includes all indices along with the specification limits and a judgement if lab capability is low, medium or high.

### Linearity

Linearity calculates a linear regression using the least square error for the model  $y = a + bx$ . Linearity calculations can be carried out for multiple injections and multiple determinations. Figure 41 shows the planning dialog of the checkpoint "linearity".

#### Planning data

- Determination method:
  - Regression weighting: unweighted, weighted  $1/x$ ,

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- Residual standard deviation
- Method standard deviation

For proportionality the following entries need to be specified: the nominal value  $d$ , which describes the maximum deviation of the one-point calibration from the linear regression, the niveau specification limit  $g$ , which is the minimum concentration where the one-point calibration has to be valid, and the number of measurements to be executed at the limit  $g$ . Calculated parameters are:

- Sum of the x- and y values
- Slope
- Intercept
- Linear equation
- Residual standard deviation
- Absolute method standard deviation
- Relative method standard deviation
- Confidence interval of the slope
- y-intercept
- Coefficient of correlation ( $r$ )
- Coefficient of determination ( $r^2$ )

**Figure 41**  
Planning dialog of checkpoint "Linearity"

## Calibration function

The calibration function is the correlation between the expected value of the test characteristic, e.g. the UV absorbance (see DIN 55350 part 13), and the content, e.g. a concentration. The user can specify the maximum degree of curve fit for the calibration curve. 1st order is standard and 3rd order is the maximum (cubic curve). Figure 42 shows the planning dialog of the checkpoint “calibration function”

### Planning data

- Number of levels
- Unit of values
- Curve fit display 1-3
- Multiple injections possible
- Multiple determination possible

### Output settings for calculation

- Vector  $y = ax + b$  - curve in the case of linearity
- Square sum of the residuals (only calibration function)
- Residual standard deviation
- Mean value and standard deviation of  $y$
- Multiple correlation coefficient
- Results of F- and t-tests
- Method standard deviation

## Limit of detection and limit of quantitation

The detection limit (LOD) is the smallest amount of substance that can be detected qualitatively during one analysis with a defined statistical certainty. The quantitation limit (LOQ) is the smallest amount of a substance that can be detected quantitatively during one analysis with a statistical certainty to be determined. The quantitation limit

is higher than the detection limit. The relative error of results is required to calculate the quantitation limit. Both the detection limit and the quantitation limit can be calculated by the standard deviation of blank values (blank value method) or the residual standard deviation of regression data (calibration curve method). Only one of the two methods may be suitable for practical purposes. Both methods, however, are almost equal with respect to the detection limit. The

a calculation of LOD and LOQ based on the standard deviation of the signal and the calibration curve (slope). This is referred to as “according to ICH” in the planning dialog. Finally LOD and LOQ can be determined by “visual inspection” based on the signal-to-noise-ratio. In this case no calculations are performed and the chromatogram is attached to the validation as a bitmap (BMP format) or windows meta file (WMF format) and included in the overall report. Figure 43 shows the planning dialog of the checkpoint of detection/quantifi-

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### data

Quantitation method:  
Blank value method  
According ICH  
Calibration line method  
According to ICH  
Visual method

Headers	
Product	late night wake up drug
Test method	batch
Test criterion	According to ICH
X-Dimension	Run number
Meas. sys.	HPLC
QS-Number	fantasy
Device type	Agilent 1100
Device-No.	for serial numbers see checkpoint header
Comment	no comment

Planning data

Number of levels: 6  
Unit of values:   
Curve fit display: 1  
1: linear  
2: quadratic  
3: cubic

Multiple determination

☐ Multiple injection      Number per value: 1  
☐ Multiple determination      Number per value: 1

Calibration Function

The calibration function is the correlation between the expected value of the test characteristic, e.g. the extinction (see DIN 55350 part 13), and the content, e.g. a mass concentration.

Calibration

Calibration is the process of analysis of calibrator solutions, which are solid or gaseous standards of known content. It serves to define the calibration function.

The dependence of the signal  $y$  on the unknown variable  $x$  can be described by the general curve equation  $y = a + bx$  for the linear case. This curve equation contains two parameters: first the method blank value  $a$ , determined

Figure 42  
Planning dialog of checkpoint “Calibration Function”

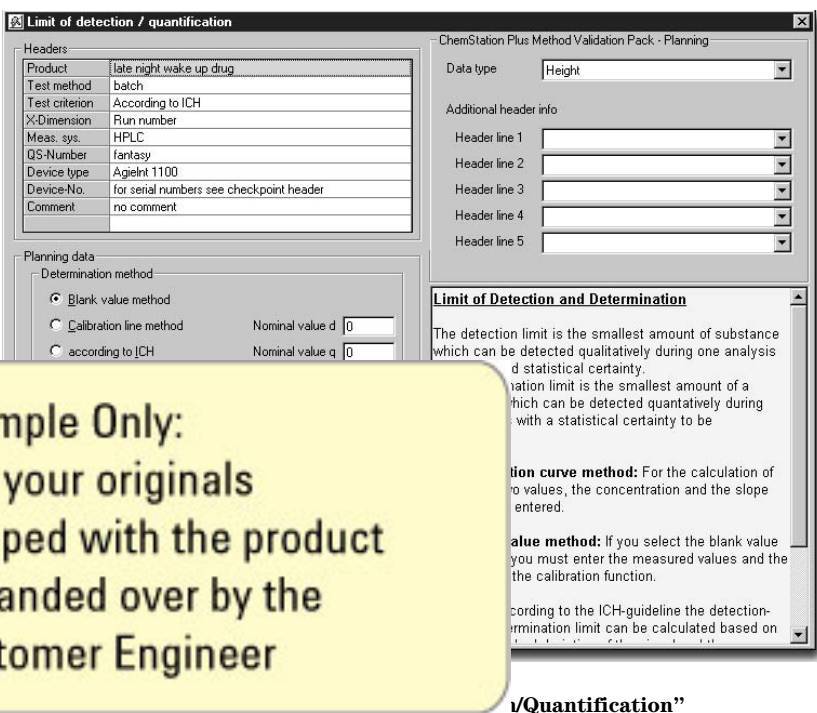
- Signal/noise ratio according to ICH
- Other data
  - Nominal values for the detection limit  $d$  and quantitation limit  $q$
  - Number of samples
  - Y-units
  - Multiple injections possible

#### Output settings for calculations

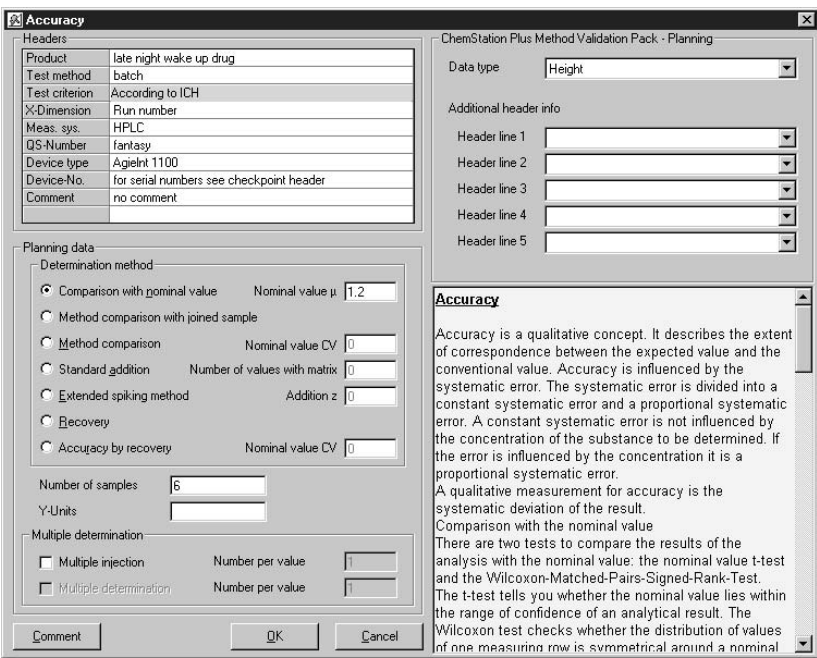
- Standard deviation
- Procedure standard
- Critical value  $y_k$
- Residual standard  $s$  (additional for calibration method)

### Accuracy

Accuracy is a qualitative measure describing the degree of correspondence between the expected value and the conventional value. Accuracy is influenced by systematic errors. The systematic error is divided into a constant systematic error and a proportional systematic error. A constant systematic error is not influenced by the concentration of the substance to be determined. If the error is influenced by the concentration, it is a proportional systematic error. A qualitative measure for accuracy of a result is its systematic deviation. Figure 44 shows the planning dialog of the checkpoint "accuracy". Method Validation Pack provides a set of different determination methods, some involving a comparison with a second method. The standard addition method is used in trace analysis and determines the matrix influence. The extended spiking method allows constant and proportional systematic errors to be determined, even when there are no samples with known



“/Quantification”



**Figure 44**  
Planning dialog for checkpoint “Accuracy”

content. It is suitable for analytical methods which consist of weighing, diluting and measuring steps. For the recovery method linearity must be given for a number of samples with different content. A nominal value for the variation coefficient VC can be entered for method comparison and for accuracy by recovery.

#### Planning data

- Determination method:
  - Comparison with nominal value  $\mu$  for the t-test
  - Method comparison of joined samples sets determined by different methods
  - Method comparison of validated methods (according to ICH)
  - Standard addition
  - Extended spiking method
  - Recovery
  - Accuracy by recovery (according to ICH)
- Other data:
  - Number of samples
  - Y-units
  - Multiple injections possible

#### Output settings for calculations

- General:
  - Result t-Test
- Joined samples:
  - Difference of value pairs
  - Mean value and standard deviation of differences
- Nominal value comparison:
  - Result of Wilcoxon test (additional for nominal value comparison)
- Extended spiking method:
  - Test quantity for a and b
  - Threshold quantity t division
- Standard additional method:
  - Result F-test
  - Result t-test

- Recovery
  - Standard deviation for a, b
  - Residual standard deviation
  - Method standard deviation
  - Test quantities  $t_a$  and  $t_b$
  - t-distribution
- Method comparison
  - comparison of mean values

#### Selectivity/Specificity

Selectivity means that an analytical method can distinguish the substance to be determined from other substances in the sample.

point “selectivity”. The selectivity is determined from the resolution values calculated by the ChemStation. Available calculation methods are tangent (according to USP, EP and ASTM), sigma, halfwidth and statistical.

#### Planning data

- Number of values
- Y-units
- Nominal value for the resolution R
- Add chromatogram bitmap
- Multiple injections possible

#### Output settings

Available data including the obtained resolution values are shown.

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Station Plus Method Validation Pack - Planning

Test criterion: According to ICH

%-Units	Run Number
Meas. sys.	HPLC
QS-Number	fantasy
Device type	Agilent 1100
Device-No.	for serial numbers see further header data
Comment	no comment

Planning data

Number of values: 6

Y-Units:

Nominal value resolution R: 1

Chromatogram:

Multiple determination

☐ Multiple injection Number per value: 1

☐ Multiple determination Number per value: 1

Additional header information

Header line 1:

Header line 2:

Header line 3:

Header line 4:

Header line 5:

Selectivity

- Selectivity means that an analytical method can distinguish the substance to be determined from other substances in the sample. Selectivity in chromatography can be described by the relative retention of analyte and interfering substance(s). Optional a chromatogram (BMP-/WMF-format) can be imported).
- Calculated value: Resolution R

Figure 45  
Planning dialog of checkpoint “Selectivity”

## Ring experiment

Ring experiments are used to prove that a method can be successfully transferred to an entirely different location (other site, company etc.) and that it delivers appropriate results. A ring experiment can be seen as a more general ruggedness test. Figure 46 shows the planning dialog of the checkpoint “Ring experiment”.

### Planning data

- Number of rows ( one row per one lab)
- Y-units
- Checkmark for same number of values per lab
- Multiple injections possible

### Output settings

- Neumann trend test
- Dixon or Grubbs test for outliers
- Variance homogeneity
- Repeatability limit
- Reproducibility limit

Lab data	
Lab	Number of values
1	6
2	6

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- Range of confidence (repeatability conditions)
- Range of confidence (reproducibility conditions)

Settings are preconfigured to useful defaults. As long as you do not have the need to enable special settings, there is no need to change anything.

## ChemStation Plus Method Validation Pack — Interaction with other ChemStation Plus modules

As described in previous sections Method Validation Pack interacts with ChemStation for data acquisition and ChemStore for result and data management.

### Interaction with ChemStation for data acquisition

If Method Validation Pack is installed in a ChemStation Plus data system ChemStation will offer additional functionality to run and execute method valida-

tion sequences. It includes two additional Method Validation menu items in the ChemStore menu (figure 47), as well as new buttons in the graphical user interface. The first button switches ChemStation into method validation mode and back to the standard mode. The second button opens the sequence import dialog.

If method validation mode is enabled, the user has access to the

method validation sequence import menu. The import window displays a list of all pending method validation sequences (MVS files) the user should have access to. The list includes status information and user assignment of the MVS files. In a client-server installation the list of method validation sequences is accessible from any ChemStation in the cluster that has Method Validation Pack installed. This means that validation planning

and data acquisition do not need to be done on the same system. Users can now select the MVS files they want to download from the list of pending files. An MVS file has an assignment to one specific user or it has no user assignment and is thereby an all-user job for all users with a valid logon and the appropriate access privileges to Method Validation Pack. As soon as a user has loaded a pending validation sequence for execution in the ChemStation, it is blocked for other users. Before running the sequence the user can add additional sequences, for example calibration runs or system suitability runs. Partially completed sequences can be set to *Finalized*, the remaining actions are deleted, the file from the pending MVS files list can be executed at any point in time by submitting them again in a custom sequence. Alternatively partially executed and not finalized MVS sequences can be reloaded and re-run after the already executed sequence lines have been manually deleted. Finalizing a MVS sequence will also lock the validation and prevent it from further modification. A validation can only be unlocked by an authorized user and requires an electronic signature.

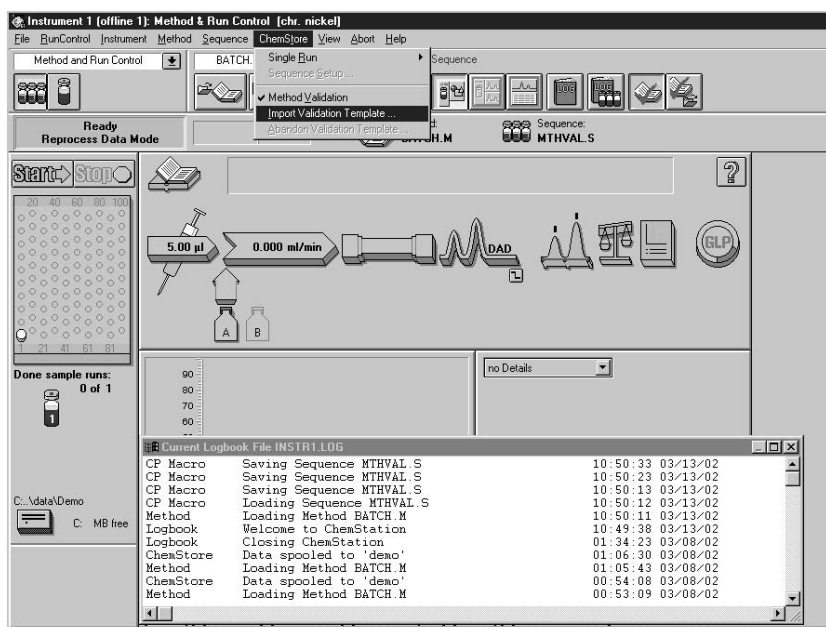
MVS sequences are created with a specific command (*Create Study and MVS for ChemStation Plus*) in the Method Validation Pack software. They are automatically built according to the validation configuration in the Method Validation Pack software - no user interaction is required. The MVS

sequence template is stored as a text document with the validation in the Document Management System (DMS) of the Method Validation Pack software. Each injection translates into one line in the sequence table; repetitive injections of the same sample receive only one sequence line but write the number of injections in the related sequence column. The MVS files automatically include information on the sample type, number of injections and sample name. The sample name references

robustness testing. A convenient way to quickly fill in the method name is the sequence fill-down wizard of the ChemStation. Additional information is stored in protected custom fields. This information displays the checkpoint name, the component name and a unique run-ID for easy identification in the sample information text dialog. These fields can only be configured and edited by the Method Validation Pack software.

To run MVS sequences the operator only fills in the vial position for the samples and starts the sequence. For further details on ChemStation functionality, please refer to ChemStation specifications, Agilent Technologies publication number 5988-5314EN.

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**Figure 47**  
Additional Method Validation menu item in the Data Acquisition ChemStation software module

## Agilent ChemStation Plus Method Validation Pack — Interaction with other ChemStation Plus modules

---

### Data management

ChemStore manages the analytical results along with the raw and meta data of the samples in a relational database. This also includes all analytical data of the method validation sequences that have been acquired in the ChemStation. The method validation data are

stored in method validation studies. Method validation studies are similar to standard studies except that they are created and modified within the Method Validation Pack. All method validation studies are visible in ChemStore. They can not be changed in ChemStore except for reanalysis. The data transfer from the

Method Validation Pack to ChemStation the Method Validation Pack software creates and, when revising data, updates a method validation study in ChemStore. The study name corresponds to the validation name. It is recommended to use short validation names as a study name is limited to 12 characters. Method Validation studies have three custom fields automatically configured with the studies. These fields are

- MV\_checkpoint - storing the Method Validation Pack checkpoint information (which test was used with this run)
- MV\_component - the name of the Method Validation Pack component in the validation - comparable to the ChemStation Plus compound.

- MV\_runID - storing a unique run identifier that allows full traceability from method validation pack results to ChemStation Plus result management. This is particularly useful for example, if you notice outliers in your method validation. In order to check the integration and decide whether

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the results and the quality of the integration. The graphical result review such as inspecting the baseline of the chromatogram or zooming in to check the integration is done in the chromatogram view of the review client. If any rework is required the data can be submitted to the ChemStation batch review user interface for graphical rework and data reanalysis as described in the section *Agilent ChemStation Plus Security Pack - Graphical Result Review and Calculation*. These steps generate a new result version that is then used for the validation instead of the initial version. If a result was obtained by applying manual integration events it will be marked as such in the validation report. The result is transferred to the data-

base and the change is documented in the run-related audit trail.

The user decides if the validation is a development validation or a final validation that must run under full 21 CFR Part 11 conditions.

In the former case, users with administrative rights can configure the level of audit trail for the

validation and the study settings within the ChemStore study. This is done within the Method Validation Pack and is similar to the study configuration in ChemStore. They can select to

Save raw data with results  
Delete raw data on the local hard disk after transfer to the database

Save method and sequence along with results

- Save chromatogram and spectra pictures with the result

In a 21 CFR Part 11 validation, all these functions are enabled for the data management options and cannot be disabled. The validation report includes a marker which clearly indicates whether the validation was carried out under 21 CFR Part 11 conditions or, under less stringent conditions, as a development validation.

If the decision was made to run a validation in development status in order to reduce the amount of information stored in the database and logged in audit trails, this decision cannot be revised at a later stage. A development validation cannot be promoted to a 21 CFR Part 11 validation.

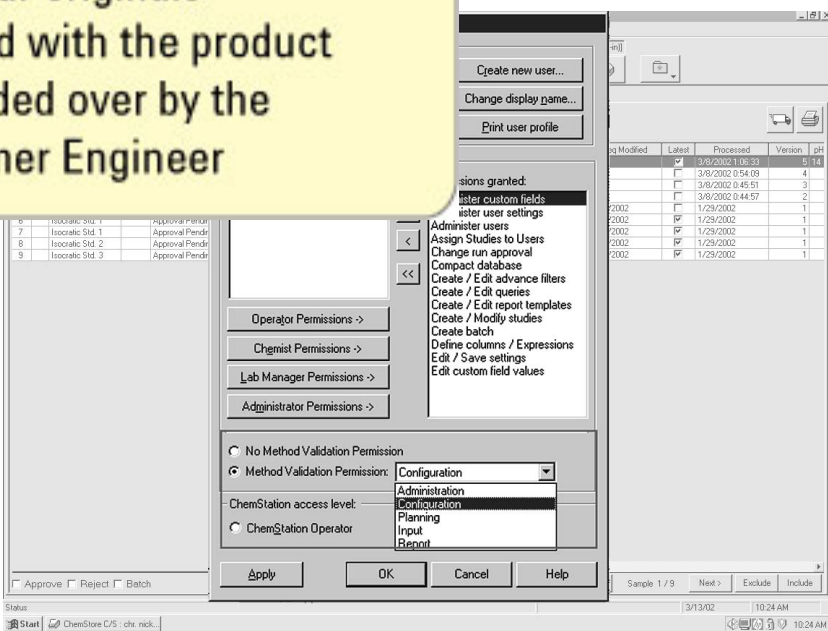
## ChemStation Plus Method Validation Pack — User Management and Access Rights

Based on the hierarchical structure of the Method Validation Pack software, the system has five user levels. They are:

- 1) **Reporting:** Logging into the system with a name and a password of level 1 (reporting) gives the user access to report output only. At this level, data changes are impossible.
- 2) **Data input:** Logging into the system with a name and a password of level 2 (data input) gives the user access to data input tasks and validation tasks (loading study data, import) and the generation of the graphics.
- 3) **Planning:** Logging into the system with a name and a password of level 3 (planning) gives the user access to all level 1 and level 2 tasks plus checkpoint planning.
- 4) **Configuration:** level 4 (configuration) gives the user access to configuration rights and all level 1-3 tasks. The user may change the configuration on a validation level only.
- 5) **Administration:** Logging into the system with a name and a password of administrator level 5 gives the user access to all functions of Method Validation Pack including the program configuration (global settings such as the default validation settings for new validations).

The user levels are part of the ChemStation Plus user administration as shown in figure 48. They are centrally configured and administered in the ChemStore database. All users have two identification components, user ID and password. One user ID is valid for all ChemStation Plus modules, so a user only has to remember

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**Figure 48**  
Central user administration for ChemStation Plus including Method Validation Pack user administration and user levels

## Agilent ChemStation Plus Method Validation Pack — Data Security

### User authorization

As mentioned under “User management”, only users with a valid ChemStation Plus user ID and password can log on to the Method Validation Pack software. The user management includes a password policy for regular password renewal and user account lockout after a specified number of unsuccessful password attempts. For details, please refer to ChemStation Plus Security Pack specification.

### Document management

Method Validation Pack includes a fully featured document management system (DMS) that stores all data in a relational database. For standalone operation, all data are stored in a VDB file, a database file that adheres to a common file format as used by MS Access. The DMS is automatically started with Method Validation Pack and runs in the background. It is used to store and maintain validation data by providing full versioning of validations and storage of all important related data such as configuration and planning information, document attachments, copies of reports and validation sequences that were generated for full traceability. It stores all data under the validation name as the highest hierarchical element called “document”. It is subdivided into four subsections as shown in figure 49:

- VDB section for *validation data base*—all data from planning, configuration, setup and analytical results.

- MVS section for *method validation sequences*—all ChemStation method validation sequences that have been created from the validation database.
- DOC section for *reports*—all reports are stored as doc files that have been printed for the validation database.
- PDF section for *reports in pdf*

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along with the user name, the database name and the PC host name. Each revision of each file can be recreated and reopened

for review. All DMS entries are displayed in a hierarchical list. Entries can be selected to view all properties which are displayed on the right window pane of the DMS. Additional information that is stored with each revision includes:

- name of entry,
- original path,
- label,
- type of entry (manual revision, automatic revision),
- revision number,
- revision type,
- checksum,
- status (normal, checked-out, initialized),
- user of user, user domain and computer,
- display name of user (display name),
- reason for check-in,
- check-in date, and
- date of parent entry (i.e. base node entry).

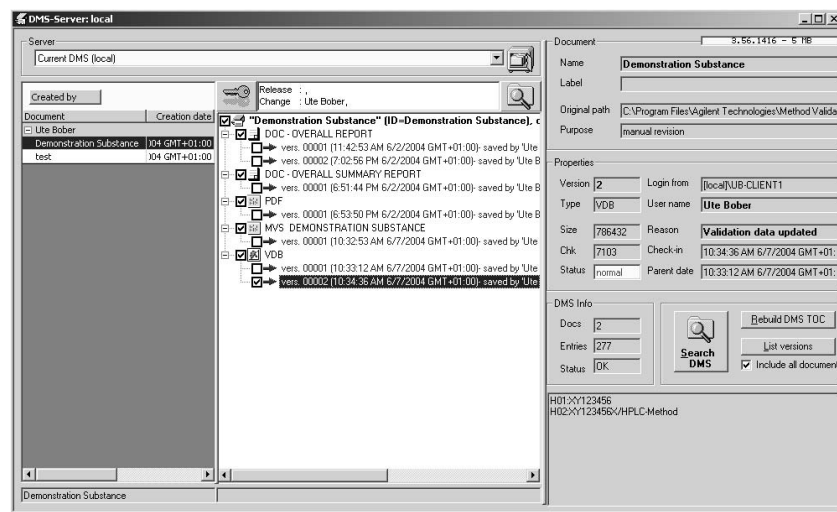


Figure 49  
Method Validation Pack document management system DMS

A click in the checkbox of a section offers review of any document revision. Clicking a version child node once displays its properties. Double-clicking a validation (VDB-file), or clicking on its selection field, will restore the selected version. Documents and MVS files can be displayed in a review window, allowing to zoom, print, export or copy the selected document. The actions depend on the type of entry: documents are displayed in a review window, validations are displayed in the file system.

#### DMS with standalone

Standalone systems will require managing multiple databases. The system will allow a user to create a new DMS file after the size limit is exceeded. A DMS or validation that has passed its size limit can still be selected for review. If the system has more than one DMS database, the user is automatically connected to the current DMS as shown in figure 50. If there is a need to review old data the user has to select the DMS database from the dropdown list of available databases to connect to it. The DMS databases are sorted and named by date.

#### DMS for client/server systems

Client/Server system using an Oracle relational database will store all validations in the same database. A list of all available validations displays when selecting to open an existing validation. The user



**Figure 50**  
Selection dropdown window for database connection

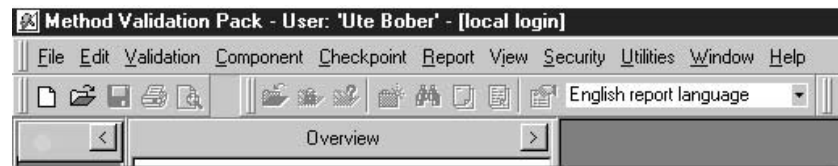
selects the validation from the list with a simple click on the actual validation. If users open older revisions of a validation the validation is opened in a locked status as read-only. Only saving it as the latest revision removes the

folder permissions. It offers write-only access to all authenticated users and only an administrative user has full access to the DMS directory. Understanding and using file security is particularly important in standalone installations where data is stored in the local database. In a client-server installation, the default storage location should be an Oracle database that is stored on a separate server and that is not accessible to any software operator.

#### Permanent display of current

Method Validation Pack always displays the current user in the title bar. The system displays the current user name and the database information. The database is either displayed as local login for a standalone database connection or as the Oracle database alias if the system is connected to an Oracle database, as shown in figure 51.

Method Validation Pack always displays the current user in the title bar. The system displays the current user name and the database information. The database is either displayed as local login for a standalone database connection or as the Oracle database alias if the system is connected to an Oracle database, as shown in figure 51.



**Figure 51**  
Permanent display of current user name, and database connection with Method Validation Pack software

# Agilent ChemStation Plus Method Validation Pack — Audit trails and change documentation

## Audit-trails

The Method Validation Pack audit-trail tracks all actions that users execute during program operation. The audit-trail is user-independent, can not be modified nor deleted and it is completely system-generated. Method Validation Pack has three different audit-trail levels, as shown in figure 52:

- program audit-trail,
- default validation audit-trail, and
- validation audit-trail

The default display size of the audit-trail can be configured in the audit-trail window. The entries for display must be between 25 and 30000. All audit-trail entries can be printed to a printer. The audit trail can also be used for the overall validation report. This is a global setting and has to be enabled for generating the report.

For easier searching through the audit trail, users can group the audit-trail entries. All audit-trail column headers are available as grouping criteria. The grouping functionality uses a simple drag-and-drop functionality to enable or disable grouping. The user only drags the column header into the grouping section and receives a sorting of the complete audit-trail according to the column entries. As an example, the audit-trail should be arranged by user name. The system displays all user name entries as parent nodes. A simple click on the node expands the audit trail to now display all audit-trail entries for the selected user as shown in figure 53.

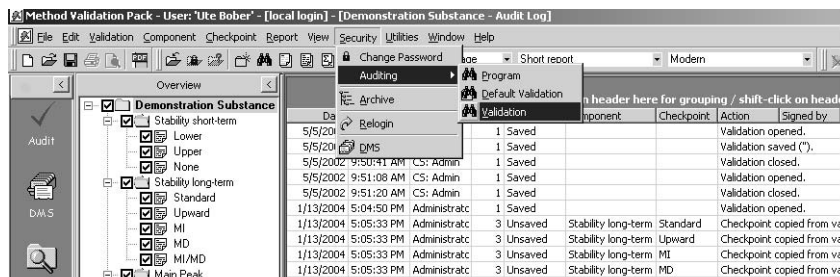


Figure 52  
Three levels of audit-trail with Method Validation Pack software

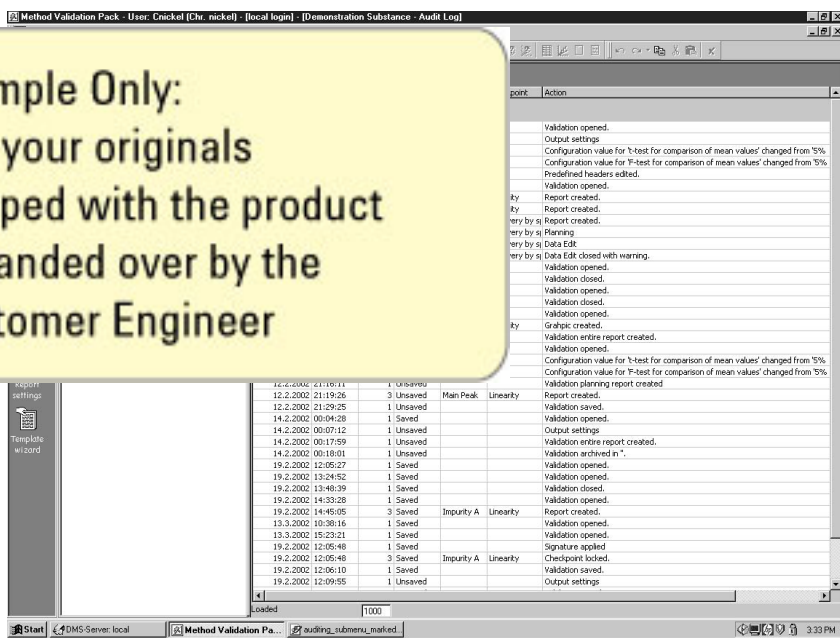


Figure 53  
Grouping of audit-trails, in this example grouped by user

## Audit-trail details

The validation and default validation audit-trails display all actions that are related to a validation or the default validation template which is applied when creating new validations.

Both audit-trails offer the following information where each item displays its data in a separate column:

- Date and time of action
- Printed user name

- Level of action (e.g. level 4 for configuration changes)
- Status of the change ( saved or unsaved)
- Affected component
- Modified checkpoint
- Action (the audit-trail lists the menu if the user did only open the menu without changes and it lists any parameter change with the old and the new value)
- Display name of the signer and signature comment

The program audit trail will be described in more detail in the following section.

### Default validation audit-trail

The default validation audit-trail refers to the general configuration of validations. It covers all changes that are not related to a specific validation database but apply to the validation template that all new validations are based on upon creation. The audit-trail contains all new validation parameters, new validation outputs, and changes to these settings. Changes to these settings are displayed in the default validation audit-trail.

### Validation audit-trail

The Validation audit-trail records all actions on the actual validation data.

### Program audit-trail

The program audit-trail is designed to track all actions that relate to the general program operation such as save and logon actions. The program audit-trail table items are:

- Date and time
- User ID
- Validation name
- Storage location of the actual validation snapshot copy
- Action (Program start and stop, user logon and logoff, IQ execution, validation opening, use of import mask for data entry, and program options)

### Validation locking and electronic signatures

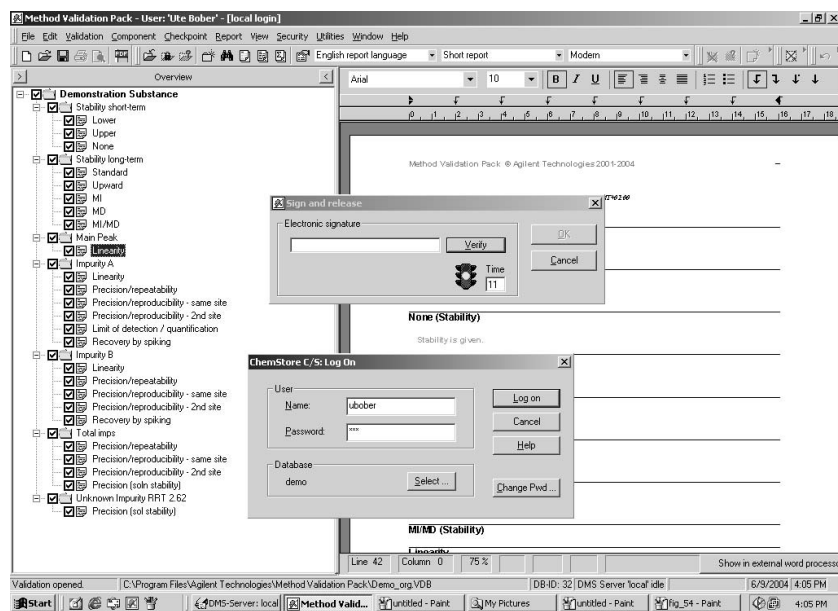
After completion of a single checkpoint, an entire component or a complete validation, a validation can be locked to the same extent to prevent further modification. To avoid locking of incomplete items, the application software will display a warning message and close the lock dialog without

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the graphics. Every locking action automatically creates a new revision of the validation in the

DMS system. Only users with an access level 3 (planning) or higher have access to the locking functionality. Each locking action requires an electronic signature. The electronic signature uses the password/ user ID combination as defined by the FDA (figure 54). The sign-off dialog comes with a time limit of 45 seconds. If the signature was not executed during this period, the dialog will close and the validation status remains unchanged.

If an item was locked by mistake or is to be modified due to late changes in the test specifications, the lock status can be removed by a user with sufficient privileges (access level 3 or higher). For unlocking a validation, component or checkpoint the same procedure is followed as for locking. The user has to give an electronic signature to initiate unlocking.



**Figure 54**  
Executing electronic signatures with Method Validation Pack

## Agilent ChemStation Plus Method Validation Pack — Installation

---

### Prerequisites

Method Validation Pack can operate both PC-based in a standalone installation or in a networked system installation with full client-server functionality. In both scenarios, some prerequisites must be met:

### Software

ChemStation Plus standalone – For a fully integrated installation of Method Validation Pack, it is required to have the following software installed:

- ChemStation Plus standalone B.03.01 or higher or ChemStation Plus Pack rev. B.03.01 or higher
- Agilent ChemStation Plus LC, A/D, CE, CE-M, or CE-MS rev. A.10.01 or higher for data acquisition

### ChemStation Plus

If the system should operate in client-server mode, ChemStore with Oracle 9i (version 9.2.0.3.0) must be installed on the system. In the client-server installation, all ChemStation Plus modules can operate from different PCs. Their installation is completely independent and the system is fully functional as long as all required modules (see above) are installed within this cluster and they can connect with each other.

### Non-Agilent software

- MDAC 2.8 (Microsoft Data Access Components 2.8) (installed by ChemStore)
- Adobe Acrobat Reader 5.0 (part of standard bundle)
- Microsoft Internet Explorer 6.0

The Microsoft Data Access Components install a layer to access local databases or central database servers. Method Validation Pack uses Microsoft IJET database to save local data.

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Other ChemStation Plus modules as outlined above are also user installable for advanced users. However, Agilent recommends the installation of the ChemStation Plus modules through an Agilent-certified service engineer to prevent from any potential installation problems and for inclusion of software familiarization upon installation.

### Client-server installation

The client-server installation must include for the server

- installation of Oracle 9i server software (version 9.2.0.3.0),
- installation of ChemStore server software,
- creation of the Oracle database
- installation of Method Validation Pack software, and
- creation of Method Validation Pack tablespaces in ChemStore Oracle instance (alias "HPCS")

For every client the procedure includes the installation of Oracle 9i client software version 9.2.0.3.0, ChemStation software for data acquisition, ChemStore or Security Pack software for data management, and Method Validation Pack software.

Please note that Method Validation Pack software does not necessarily need to be installed on every client in a client-server system. If method validation is carried out on a subset of all networked ChemStation Plus clients, only those clients participating in the process of validating analytical methods must have the software installed.

Agilent offers the complete portfolio of installation, validation and training through its project services organization. This will be handled as one project where the complete service delivery is managed centrally based on the individual customer requirements.

## ChemStation Plus Method Validation Pack — Product Options and Configurations

### Standalone version

The standalone version of Method Validation Pack requires the additional installation of the ChemStation for data acquisition and the ChemStation Plus database module for data management of analytical data. The database can be ordered as G2181BA ChemStore database or as G2183AA Security Pack for full support of 21 CFR Part 11. The installation of the standalone version requires one of these products:

Description	Product No.
<b>ChemStation Plus Method Validation Pack</b> Requires but does not include ChemStore C/S or Security Pack. Allows for method validation according to DIN/ICH/USP and EP guidelines. Supports 21 CFR Part 11 (only in conjunction with ChemStation Plus Security Pack).	<b>G2184AA</b>
<b>Software module to add Agilent ChemStore C/S to an existing ChemStation for GC, LC, LC/MSD, CE or A/D.</b>	<b>G2181BA</b>
<b>ChemStation Plus Security Pack.</b> Adds the secure ChemStore C/S relational database add-on software module to the ChemStation Plus SW for A/D, GC, CE, LC and CE/LC-MSD.	<b>G2183AA</b>

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### Client/server version

Method Validation Pack client/server installation requires Oracle 9i Rev. 9.2.0.3.0. A system configuration requires ChemStore C/S server software (G1410A) for each server plus Agilent NDS Oracle user licenses (G1411A) for each named database user, one full use copy of the ChemStore client software (G2181BA) and a ChemStation Plus client license (G2186BA) for each connected client as well as copies of G2184AA for all Method Validation Pack clients. For full support of FDA's 21 CFR Part 11, replace G2181BA with G2183AA. Agilent provides all Agilent ChemStation Plus software and Oracle 9i software on Agilent CD-Rom media.

	Product No.
allows for method validation according to DIN/ICH/USP and EP guidelines. Supports 21 CFR Part 11.	<b>G2184AA</b> Qty: number of method validation systems in ChemStation Plus C/S networked data systems
Must have one copy of G2186BA or G2181BA per PC running Method Validation Pack software. For full support of 21 CFR part 11 replace G2181BA with G2183AA per server <i>NOTE: The number of Method Validation clients can be smaller than the number of ChemStation plus clients in case method validation will only execute on a subset of all networked ChemStation Plus clients</i>	
<b>ChemStore C/S server application software</b> Includes ChemStore C/S server software, Oracle 8i standard edition software, 5 Oracle application-specific named user licenses	<b>G1410A</b> Qty: one per server
<b>Oracle named user license for Agilent NDS</b> Required for each named user of the ChemStore C/S server database	<b>G1411A</b> Qty: (Required for each named user in the ChemStation Plus networked data system) -5
<b>ChemStore C/S client application software</b> Software module to add Agilent ChemStore C/S to an existing ChemStation for GC, LC, LC/MSD, CE, CE/MSD or A/D.	<b>G2181BA</b> Qty: one per server
<b>ChemStation Plus ChemStore client license</b> Includes one online ChemStation Plus license for online data acquisition and one ChemStore C/S offline data review license. Includes license and user information only. Requires but does not include ChemStation Plus software client media.	<b>G2186BA</b> Qty: Number of clients -1
<b>ChemStation Plus Security Pack.</b> Adds the secure ChemStore C/S relational database add-on software module to the ChemStation Plus software for A/D, GC, CE, LC and CE/LC-MSD. Supports 21 CFR Part 11.	<b>G2183AA</b> Qty: one per server Replaces G2181BA

# Installation, Qualification Services and Training

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## Installation and familiarization

Agilent Technologies' installation and familiarization service ensures that the Agilent ChemStation Plus is installed correctly and in the right environment.

In addition, Agilent offers a range of on-going support services to help:

- get your system up and running fast,
- resolve problems quickly,
- keep productivity high,
- extend instrument life, and
- comply with regulatory quality requirements.

## Qualification services

- Agilent Technologies offers a full range of qualification services to provide you need to satisfy requirements from such as the U.S. Food and Drug Administration (FDA), U.S. Environmental Protection Agency (EPA), the International Organization for Standardization (ISO), and the Organisation for Economic Cooperation and Development (OECD).
- Installation qualification (IQ) service
- Operational qualification/performance verification (OQ/PV) service

## Training

Agilent's ISO-registered trainings can save you time, help keep your laboratory operating costs low, broaden your capabilities, and ensure that your laboratory complies fully with regulatory and quality requirements. For your convenience, standardized courses are offered in selected locations worldwide. Onsite courses can be tailored to your specific needs.

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## Compliance

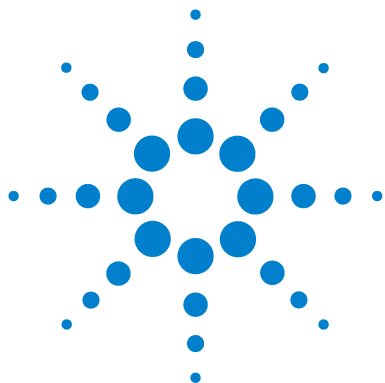
Agilent has been a worldwide Compliance leader for two decades. The unmatched experience of our experts goes into each of our compliance services. Agilent can provide you with the compliance tools, knowledge, service and support necessary to keep your lab operating smoothly and efficiently. For an overview refer to the brochure "

Can you take the heat - Don't get burned by compliance", see "[Agilent's line of proven qualification products and services](#)" in [Chapter 1](#), "Overview".

## Customer contributed documents

## 2 Design Qualification (DQ) Phase

Customer contributed documents



### 3

## Installation Qualification (IQ) Phase

### Side Preparation Specification Checklist

Agilent 1200 Series Liquid Chromatograph Hardware Site Preparation Specification

Agilent 1200 Series LC/MSD G1956A/B, G2908BA, G3218AA, G3218BA Site Preparation Specification

Agilent ChemStation Software Modules G2070BA, G2071BA, G2072BA, G2170BA, G2171BA, G2180BA Software Site Preparation Specification B.02.01

Agilent ChemStation Software Modules G2070BA, G2071BA, G2072BA, G2073BA, G2170BA, G2171BA, G2180BA, G2090BA, G2710BA, G1601BA, G2201BA B.02.01 Upgrade Site Preparation Checklist

### Installation Qualification

Agilent 1200 Series Liquid Chromatograph Hardware and Software Installation Checklist

Agilent LC and CE ChemStation Software G2170BA, G2171BA, G2175BA, G2180BA, G2185BA, G211601BA, G2172BA, G2205BA Software Installation Checklist B.02.0x

### Familiarization Checklist

Agilent 1200 Series Liquid Chromatograph Familiarization Checklist

Agilent 1200 Series Liquid Chromatograph Scorp of Work Installation and Familiarization

### Declaration of Conformity and System Validation

Declaration of Conformity According to ISO/IEC Guide 22 and CEN/CENELEC EN 45014

Declaration of Conformity to manufacturing Specifications  
ChemStation Declaration of System Validation

ChemStation Installation Verification Report

Customer contributed documents



### **3    Installation Qualification (IQ) Phase**

For the items marked with a \* example pages are added. It is the responsibility of the user to replace these with the originals. The user should feel free to add further documents, e.g. not supplied by Agilent Technologies whenever he thinks this is appropriate.

## Side Preparation Specification Checklist

**3**    **Installation Qualification (IQ) Phase**  
Side Preparation Specification Checklist

## **Agilent 1200 Series Liquid Chromatograph Hardware Site Preparation Specification**



## Hardware Site Preparation Specification

### Purpose of Procedure

Your site must meet this specification or set of requirements to assure a successful and timely installation of your Agilent instrumentation. This document is designed to prevent delays during installation, familiarization, and the initial use of the system in your application. This document outlines the supplies, consumables, space and utility requirements for a 1200 LC. It also recommends tools and consumables that may help you get started. Use this document along with the 1200 Installation documentation and Consumable Catalog. This information is also available from Agilent Technologies, Inc.'s website (<http://www.agilent.com>).

### Customer Responsibilities

Make sure your site meets this specification, including: the necessary space, electric outlets, gases, tubing, operating supplies, consumables and other usage dependent items such as columns, vials, syringes and solvents (HPLC Grade Isopropanol, Acetonitrile and water) required for the successful installation of instruments and systems. If Agilent is delivering installation and familiarization services, users otherwise, they will miss important operational, maintenance and

### Important Information

If you have problems in providing office for assistance. Assistance

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contact your local Agilent Technologies contracted separately.

### PLEASE NOTE:

Some of the instrumentation, you generate a system are not sold as individual parts.

For example, if you ordered a:

- G1354A, you will receive a G1311A (Quat. Pump) and a G1322A (Micro Vacuum Degasser)
- G1382A, you will receive a G1376A (Capillary Pump) and a G1379B (Micro Degasser)
- G2225A, you will receive a G2226A (Nano Pump) and a G1379B (Micro Degasser)

Some of the individual modules that

If you have ordered a bundled system or if you have problems in identifying the individual modules that are part of your system, please contact your sales representative for information about the individual modules that generate this system.

## Hardware Site Preparation Specification



### Dimensions and Weight

Select the laboratory bench space before your system arrives. Pay special attention to the total height requirements. Avoid bench space with overhanging shelves. Pay special attention to the total weight of the modules you have ordered. Make sure that your laboratory bench can support this weight.

Module	Weight		Height		Depth		Width	
<b>G1310A/G1311A Iso. / Quat. Pumps</b>	11 kg	25 lbs.	14 cm	5.5 in	43.5 cm	17 in	34.5 cm	13.5 in
<b>G1312A Binary Pump</b>	15.5 kg	34 lbs.	18 cm	7 in	43.5 cm	17 in	34.5 cm	13.5 in
<b>G1376A Capillary Pump G2226A Nano Pump</b>	17 kg	39 lbs.	18 cm	7 in	43.5 cm	17 in	34.5 cm	13.5 in
<b>G1322A / G1379B Degassers</b>	7.5 kg	16.5 lbs.	8 cm	3 in	43.5 cm	17 in	34.5 cm	13.5 in
<b>G1361A Preparative Pump</b>	15 kg	32.9 lbs.	20 cm	8 in	43.5 cm	17 in	34.5 cm	13.5 in
<b>G2258A Dual Loop Autosampler</b>						17 in	34.5 cm	13.5 in
<b>G1329A/G2260A Autosamplers</b>						17 in	34.5 cm	13.5 in
<b>G1367B/G1377A High Performance Autosamplers</b>						17 in	34.5 cm	13.5 in
<b>G1330B ALS Thermostats</b>						17 in	34.5 cm	13.5 in
<b>G1316A Thermostatted Column Compartment</b>						17 in	41 cm	16 in
<b>G1314B/C Variable Wavelength Detectors</b>						17 in	34.5 cm	13.5 in
<b>G1315B/C Diode-Array Detectors</b>						17 in	34.5 cm	13.5 in
<b>G1365B/C Multiple Wavelength Detectors</b>	11.5 kg	26 lbs.	14 cm	5.5 in	43.5 cm	17 in	34.5 cm	13.5 in
<b>G1321A Fluorescence Detector</b>	11.5 kg	25.4 lbs.	14 cm	5.5 in	43.5 cm	17 in	34.5 cm	13.5 in
<b>G1362A Refractive Index Detector</b>	17 kg	38 lbs.	18 cm	7 in	43.5 cm	17 in	34.5 cm	13.5 in
<b>G1364B/C/D Fraction Collectors</b>	17 kg	38 lbs.	18 cm	7 in	43.5 cm	17 in	34.5 cm	13.5 in

Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

## Hardware Site Preparation Specification



### Environmental Conditions

Operating the LC System within the recommended temperature ranges insures optimum instrument performance and lifetime. Performance can be affected by sources of heat and cold from heating, air conditioning systems, or drafts.

**Please Note:**

The site's ambient temperature conditions must be stable for optimum performance of the system's modules (as specified in the "Performance Specifications" section of each module's Reference Manual). Temperature changes of 2°C / hour or less (as defined by ASTM conditions) are required to achieve best possible baseline stability. Higher variations will definitely result in higher signal drift and wander of the baseline.

Module	Operating temp range	Operating humidity range
G1314B/C, G1315B/C, G1316A, G1322A, G1365B/C, G1362A	0 to 55°C (32 to 131°F), constant temperature.	< 95%, non-condensing
G1379B	0 to 45°C (32 to 113°F)	< 95%, non-condensing
G1330B, G1361A, G1364B/C/D, G2258A	4 to 40°C (39 to 104°F)	< 95%, non-condensing
G1321A	0 to 40°C (32 to 104°F), constant temperature	< 95%, non-condensing
All other modules		< 95%, non-condensing



### Power Consumption

**PLEASE NOTE:**

An AC power outlet is required.  
All Agilent 1200 modules have a power range of 100-240 VAC, +/- 10%.

**Example Only:**  
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(Applicable)  
Modules operate with line voltages in the

Module	Consumption [VA]	Consumption [W]	Power BTU
G1310/11A Iso. / Quat. Pumps	180 VA	55 W	188
G1312A Binary Pump	220 VA	74 W	253
G1376A Capillary Pump G2226A Nano Pump	220 VA	75 W	256
G1361A Prep Pump	250 VA	210 W	717
G1379B Micro Degasser	30 VA	30 W	102
G1322A Degasser	30 VA	30 W	102
G1329A, G2260A ALS	300 VA	200 W	683
G1367B/G1377A High Performance Autosamplers	300 VA	200 W	683
G2258A Dual Loop Autosampler	260 VA	210 W	717
G1330B Sample Thermostat	260 VA	210 W	717
G1316A Therm Column Comp	320 VA	150 W	512
G1314B VWD	220 VA	85 W	290
G1315B DAD	300 VA	125 W	427
G1315C DAD	160 VA	130 W	546
G1365B MWD	300 VA	125 W	427
G1365C MWD	160 VA	130 W	546
G1362A RID	160 VA	65 W	222
G1321A FLD	180 VA	70 W	239
G1364B/C/D Fraction Collectors	200 VA	180 W	614

## Hardware Site Preparation Specification



### *Other considerations*



### **Module Stacking**

#### **Bench Space:**

The modular dimensions and weight allow the instrument to be placed on almost any laboratory bench. The instrument requires a space of at least 2.5 cm (1.0 inch) on both sides, and approximately 8 cm (3.1 inches) at the rear for the circulation of air and room for electrical connections.

If the bench is to support a configuration of modules, the total weight of all the modules must be considered.

**Ensure that all 1200 series modules are properly secured** to defeat the leak detection system.

#### **Recommended Stacking Configuration**

A single-stack configuration is recommended.

- \* The height of the stack does not exceed 1.8 m (6 ft).
- \* The system does not include a G1330B thermostat module.

A multiple stack configuration **must** be used if:

- \* The stack of 1200 modules is too high, resulting in a safety problem.
- \* The system includes a thermostatted sampler or fraction collector.

#### **PLEASE NOTE:**

The thermostatted version of all samplers and the fraction collector include the G1330B thermostat module. The thermostat module must be placed directly under the sampler or the fraction collector to be thermostatted. It is recommended that the thermostat module is positioned as the bottom module of the stack, directly on the laboratory bench. Any stack containing a G1330B thermostat module needs at least 25 cm (10 inches) of space on either side to guarantee proper ventilation.

#### **PLEASE NOTE:**

Try to avoid stacking configurations that result in excessive volumes between sampler and column, and between column and detector(s) to avoid potential problems related to excessive delay volume or peak broadening.

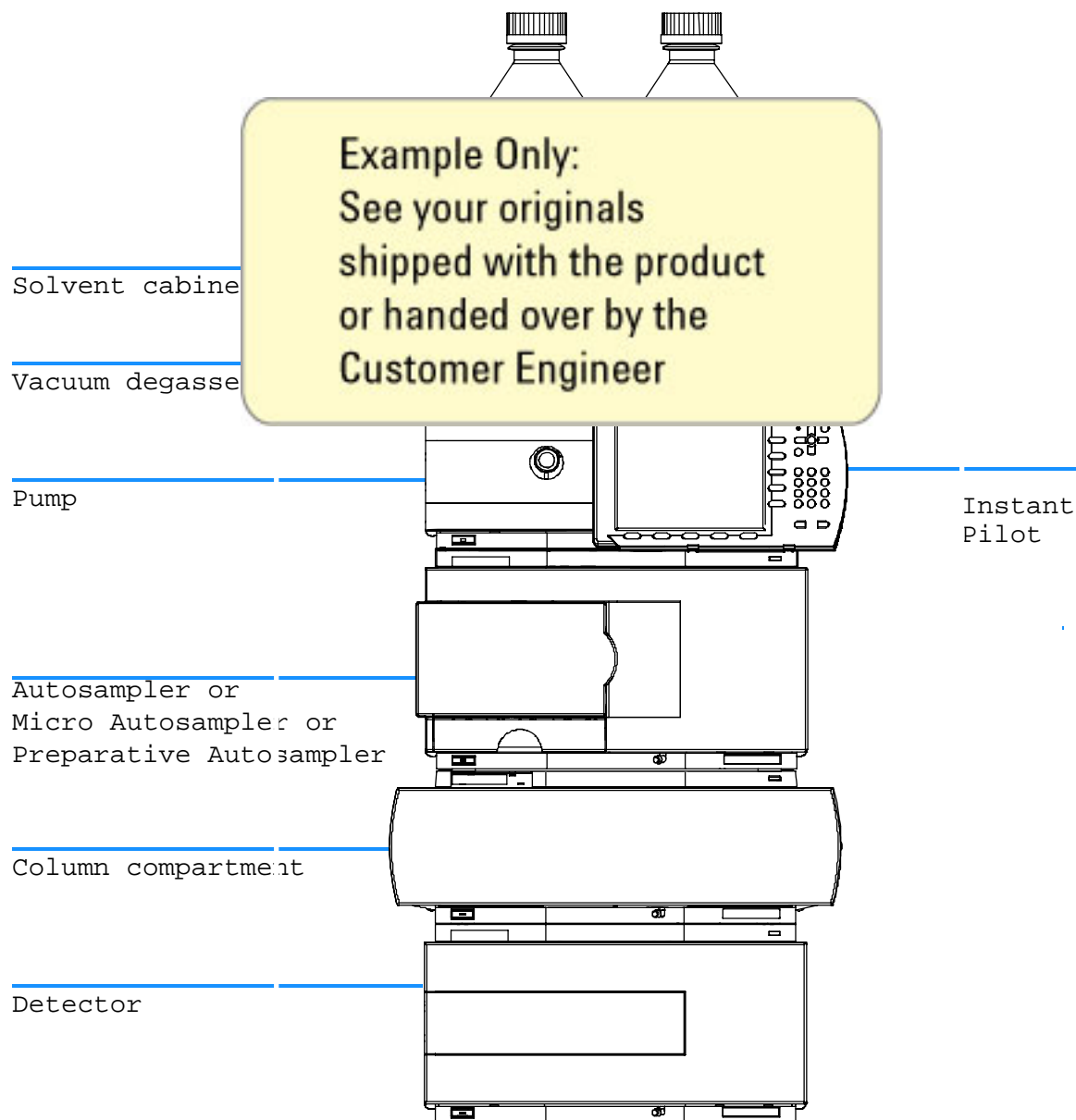
Please refer to figures 1, 2, 3 and 4 for recommended stacking configurations. The figures just show a selected number of recommended configurations. Other module setups might be possible, but may require additional connecting capillaries.

**Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer**



Hardware Site Preparation Specification

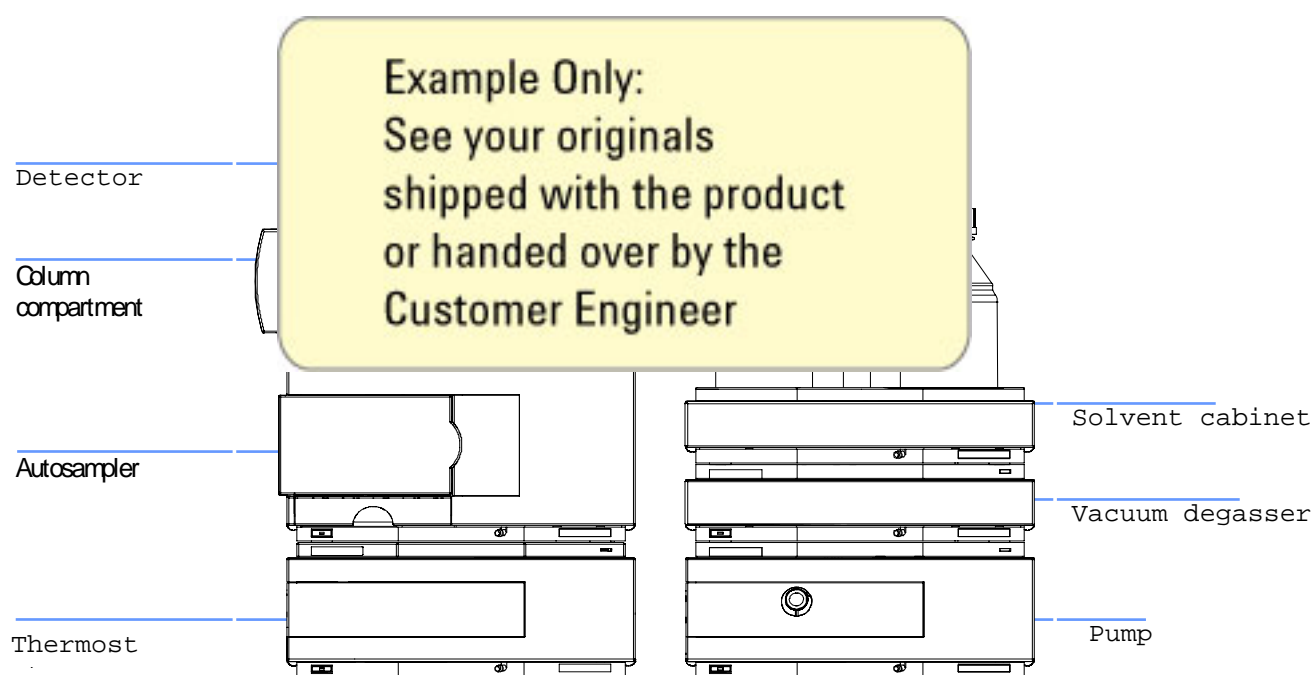
Figure 1  
Recommended 1-Stack Configuration





Hardware Site Preparation Specification

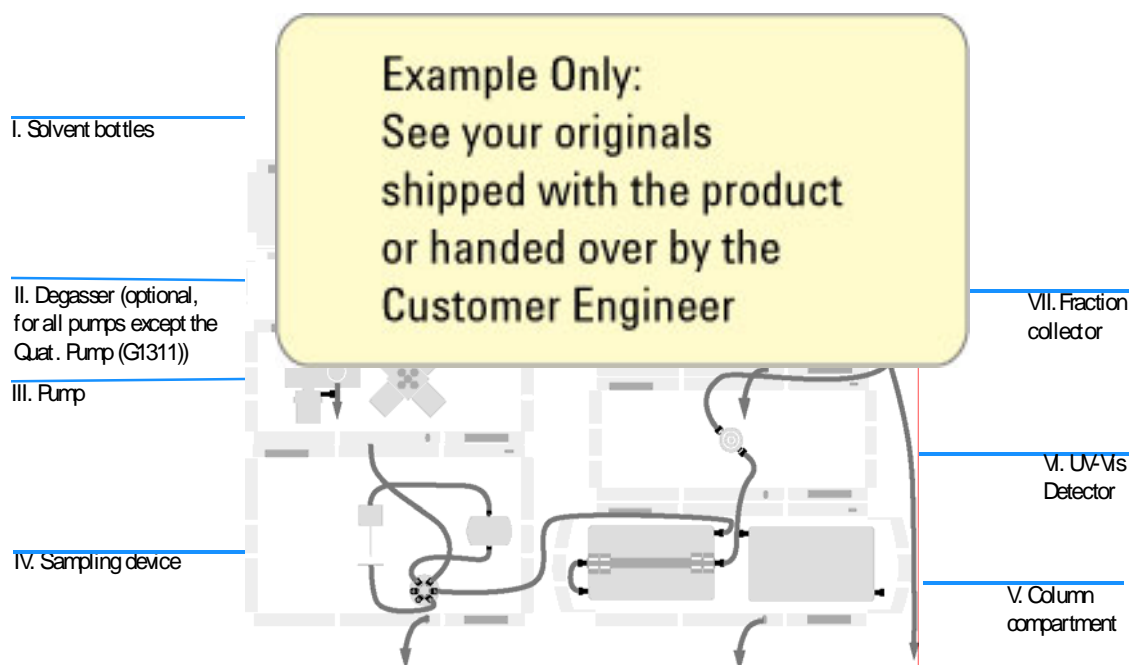
**Figure 2**  
**Recommended 2-Stack Configuration (with Thermostat)**





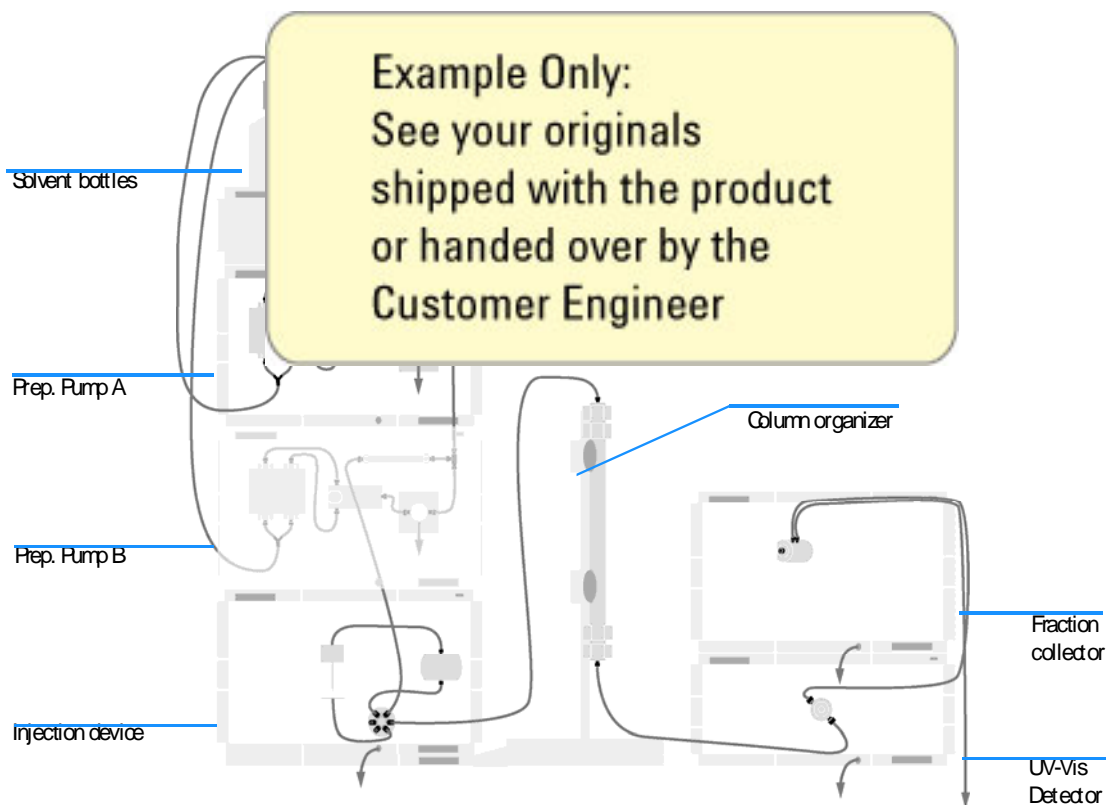
Hardware Site Preparation Specification

**Figure 3**  
**Recommended 2-Stack Configuration with Fraction Collector (Analytical Scale System)**



Hardware Site Preparation Specification

**Figure 4**  
**Recommended 2-Stack Configuration with Fraction Collector (Preparative Scale System)**



## **Agilent 1200 Series LC/MSD G1956A/B, G2908BA, G3218AA, G3218BA Site Preparation Specification**



## Site Preparation Specification

### Purpose of Procedure

To ensure that the installation site is properly evaluated and prepared with the appropriate utilities, consumables and supplies for the successful installation of Agilent instruments and systems.

### Customer Responsibilities

Customers should ensure that all necessary operating supplies, consumables and usage dependent items such as columns, vials, syringes, solvents and buffers required for the successful installation of instruments and systems are available. Installation sites should be prepared in accordance with the following specifications. An Agilent customer engineer will call approximately 2 weeks prior to installation to confirm site readiness.

### Important Information

This checklist is designed to be used in conjunction with the Agilent 1200 Series LC/MSD Site Preparation Manual. If you have problems providing any of the following, please contact your local Agilent sales office for assistance. Assistance with user specific applications may be provided but should be contracted separately. Users of the instrument should be present throughout the installation and familiarization otherwise important operational, maintenance and safety information may be missed.

### Procedure Checklist



#### Agilent G1956A/B Mainframe:

##### footprint:\*

Depth: 62.3 cm    Width: 64.0 cm  
24.5 in            25.2 in

Tick Boxes

☐

##### maximum cabinet dimensions:\*\*

Weight: 63.1 kg    Height: 57.5 cm  
138.75 lb            22.6 in

Depth: 68.83 cm    Width: 73.0 cm  
27.1 in              28.75 in

☐

#### E1M18 Mechanical Pump:

Weight: 32.0 kg    Height: 23 cm  
70.4 lb              9.2 in

Depth: 51.0 cm    Width: 17.0 cm

☐

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or handed over by the  
Customer Engineer

☐

Depth: 9.5 cm    Width: 18.0 cm  
3.7 in              7.1 in

☐

#### Agilent G1971A APPI Source:

Weight: 1.7 kg    Height: 23 cm  
3.75 lb              9.2 in

Depth: 13.0 cm    Width: 18.0 cm  
5.1 in              7.1 in

☐

#### Agilent G1978A Multimode Source:

Weight: 2.29 kg    Height: 23 cm  
5.05 lb              9.2 in

Depth: 13.0 cm    Width: 18.0 cm  
5.1 in              7.1 in

☐

\* The footprint dimensions represent the minimum dimensions of the supporting surface. This surface must also be relatively vibration free and capable of supporting at least 65 kg (143 lbs).

\*\* Maximum cabinet dimensions are for an Agilent G1956A/B with an Agilent G1947A APCI, G1971A APPI, or G1978A Multimode source installed. At least 30 cm (1 ft) to the left of the cabinet and at least 55 cm (1.8 ft) above the cabinet must be added to these dimensions to provide adequate instrument access.



## Site Preparation Specification



### Environmental Conditions

**Temperature:** 15 to 35 °C (59 to 95 °F)  
at constant temperature (variations < 3 °C/hr).

**Humidity:** < 95% relative, non-condensing

Tick Boxes



### Power

**Americas & Japan:** 200 to 220 VAC; 1100 VA max<sup>1</sup>

**Europe & Asia Pac:** 220 to 264 VAC; 1500 VA max<sup>1</sup>

**G1971A APPI Source:** 110 - 240 VAC; 15 VA max<sup>2</sup>

**G1978A MM Source:** 110 - 240 VAC; 15 VA max<sup>2</sup>



**N<sub>2</sub> Generator:** 90-110 VAC; 15 VA max<sup>3</sup>  
108-132 VAC; 15 VA max<sup>3</sup>  
207-253 VAC; 15 VA max<sup>3</sup>

All power: 50/60 Hz +/- 5%

<sup>1</sup>Single outlet for LC/MSD. See LC/MSD Site Preparation Manual, G1956-90098 for power cord configurations.

<sup>2</sup>For use with the G1971A APPI Source or G1978A MM Source.

supply.

supply.

pressor

Example Only:  
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shipped with the product  
or handed over by the  
Customer Engineer



98.0% or better - N<sub>2</sub> gas generator or  
liquid N<sub>2</sub> Dewar.

Balance of impurity should consist of oxygen and/or argon. Gas must be hydrocarbon free (< 0.1 ppm).

**Outlet Pressure:** 80-100 psi. A 1/4" Swagelok outlet (male) fitting is required to connect the LC/MSD.

**Volume:** Up to 15 liters/min.



### Laboratory Supply Requirements

**Mobile Phases:** Water, Methanol, Isopropanol, Acetonitrile<sup>1</sup>



**Purity:** HPLC-grade or better

**Buffers:** Ammonium Formate<sup>2</sup>

**Acids:** Acetic or Formic Acid<sup>3</sup>

**Purity:** Ammonium formate, 97% or better

Acetic acid, 99.7% or better

Formic acid, 96% or better

<sup>1</sup>Methanol/water required for G1956B installation.

Organic/water required for G1956A installation.

<sup>2</sup>Required for G1956B installation.

<sup>3</sup>Optional for G1956A installation.

**Site Preparation Specification*****Exhaust Venting Requirements***

**Capacity:** Up to 15 liters/min. total.

**Connections:** Separate 1/2" hose barbs required for rough pump and ion source (ES, APCI, APPI or MM).

<sup>1</sup>A 20ft. length of 1/2 inch i.d. Tygon™ tubing is included for venting source exhaust (drain bottle) and rough pump. (Sufficient for two 10 foot lengths.)

**Tick Boxes*****Remote Diagnostics***

**Phone:** One analog phone line is recommended to provide remote diagnostics capability for the LC/MSD. A second phone line is also strongly recommended for communication with the system operator.



**Example Only:**  
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**3**    **Installation Qualification (IQ) Phase**  
Side Preparation Specification Checklist

**Agilent ChemStation Software Modules G2070BA, G2071BA,  
G2072BA, G2170BA, G2171BA, G2180BA Software Site Preparation  
Specification B.02.01**



**Software Site Preparation Specification B.02.01**

**Purpose of Procedure**

To assure that the installation of Agilent instruments and systems can be completed successfully by careful preparation and evaluation of the installation site and by ensuring the availability of appropriate utilities, consumables and supplies.

**Customer Responsibilities**

Customers should ensure that all necessary operating supplies, consumables and usage dependent items such as columns, vials, syringes and solvents required for the successful installation of instruments and systems are available. Installation sites must be prepared in accordance with the following specifications.

**Important Information**

If you have problems in performing any of the following, please contact your local Agilent office for assistance. Assistance with specific applications may be provided but should be confirmed separately. Users of the instrument should be present throughout the installation and familiarization otherwise important operational, maintenance and safety information may be missed.

**Procedure Checklist:**

**Software Requirements**

- ☐ Windows 2000 SP4 or Windows XP Professional SP2 \*
- ☐ Administrator logon required to the ChemStation PC.
- ☐ TEMP variable points to an existing directory (e.g. TEMP=C:\TEMP)
- ☐ Check if a printer driver is installed on the system
- ☐ Verify that the regional settings are set to English-US

**Hardware Requirements**

- ☐ All PC hardware needs to be listed

- ☐ A printer supported by the current version of the ChemStation. For further information please contact your local service representative.
- ☐ The voltage setting of the computer system and the power cables have to be correct.

\*Detailed information on how to set up Windows XP Professional for optimal ChemStation usage is located on the ChemStation CD-ROM under the manuals\installation\Configure and Maintain your Agilent Computer directory.

Please verify if the instrument supports GPIB connection.

**Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer**

- ☐ at least 512 MB of RAM for a single instrument 2D or 3D configuration
- ☐ CD-ROM drive
- ☐ hard-disk with at least 40 GB free capacity
- ☐ SVGA or better graphics adapter and monitor (recommended resolution 1280 x 1024), True Color
- ☐ 82350A/B GP-IB card available with one free IRQ on the PC and one free PCI slot \*\* or
- ☐ LAN interface with TCP/IP protocol installed and LAN card (J4100A JetDirect card or G1369A LAN card) for instrument available.

**Agilent ChemStation Software Modules G2070BA, G2071BA,  
G2072BA, G2073BA, G2170BA, G2171BA, G2180BA, G2090BA,  
G2710BA, G1601BA, G2201BA B.02.01 Upgrade Site Preparation  
Checklist**



## B.02.01 Upgrade Site Prep Checklist

### Purpose of Procedure

To assure that the upgrade of Agilent instruments and systems can be completed successfully by careful preparation and evaluation of the installation site and by ensuring the availability of appropriate utilities, consumables and supplies.

### Customer Responsibilities

Customers should ensure that necessary operating supplies, consumables and usage dependent items such as columns, vials, syringes and solvents required for the successful installation of instruments and systems are available. Installation sites should be prepared in accordance with the following specifications.

### Important Information

If you have problems in providing any of the following, please contact your local Agilent office for assistance. Assistance with user specific applications may be provided but should be contracted separately. Users of the instrument should be present throughout the installation and familiarization otherwise important operational, maintenance and safety information may be missed.

### Additional Information

For detailed steps to perform an upgrade installation refer to the "Upgrade Preparation Guide for Rev. B.02.01 ChemStation" (P/N G2170-90226).

### Procedure Checklist:

#### Software Requirements

- ☐ Windows 2000 Professional SP4 or Windows XP Professional SP2 \*
- ☐ Administrator logon required to the ChemStation PC
- ☐ TEMP variable points to an existing directory (e.g. TEMP=C:\TEMP)
- ☐ Check if a printer driver is installed

**Example Only:**  
See your originals  
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or handed over by the  
Customer Engineer

- ☐ Microsoft Windows compatible pointing device
- ☐ Pentium IV processor operating at 1.5 MHz or higher for LC, LC/MS and GC systems
- ☐ At least 512 MB of RAM for
  - 2D instrument configuration
  - 3D instrument configuration
  - LC/MS instrument configuration
  - instrument configuration with ChemStore C/S
- ☐ CD-ROM / DVD-ROM drive
- ☐ Hard-disk with at least 40 GB free capacity
- ☐ 1280x1024 recommended resolution or better graphics adapter and monitor, True Colors
- ☐ 82350A/B GP-IB card available with one free IRQ on the PC and one free PCI slot \*\*.

- ☐ Available LAN interface with TCP/IP protocol installed and a LAN card (J4100A JetDirect card, G1369A LAN card or equivalent) for the instrument, if needed.
- ☐ A printer supported by the current version of the ChemStation. For further information please contact your local service representative or see the ChemStation installation manual for your appropriate technique.

The voltage setting of the computer system and the power cables has to be correct.

Detailed information on how to set up Windows XP Professional for optimal ChemStation usage is located on the ChemStation CD-ROM under the manuals\installation\Configure and Maintain your Agilent PC directory.

\*Please verify if your instruments support GPIB connection.



## B.02.01 Upgrade Site Prep Checklist

### Instrument Hardware Requirements LC, GC and LC/MS

- ☐ Check if Firmware revisions of instruments and modules are appropriate for ChemStation B.02.01.

#### For LC systems only:

- ☐ If Firmware is not current, ask customer to upgrade to minimum Firmware A.06.02/B.01.02 required with Rev. B.02.01 ChemStation. Please use the record outline "1100/1200 IQ Attachment Form". This document is available from the EPI Warehouse @ <http://whadmin.cos.agilent.com/AdvPubForm.asp> by searching for "1100/1200 PM Check". The 1100/1200 IQ Attachment Form AND the 1100/1200 PM Check will be retrieved. The 1100/1200 IQ Attachment Form is to be used only once.

- ☐ The FW upgrade process is described in the manual coming with the FW upgrade tool, placed on the ChemStation CD-ROM.

#### For LC/MS systems only:

- ☐ Update the LC/MSD firmware by running the executable c:\Chem32\MS\FIRMWARE\msupdate.exe while connected to the LC/MSD.
- ☐ Before upgrading the LC/MSD ChemStation to revision B.02.01, perform a dual polarity Autotune to verify instrument tune performance and to generate a record of current tune parameters.

#### For GC systems only:

GC Column Catalog: A GC Column Database Utility is available to transfer user-defined GC columns from G2070AA to G2070BA ChemStation.

User-defined column entries in the GC Column catalog are not transferred automatically during an upgrade from G2070AA to G2070BA ChemStation. The GC Column Database Utility can be used after the upgrade to transfer the user-defined GC Columns.

**Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer**

For GC systems only: This document is available from the EPI Warehouse @ <http://whadmin.cos.agilent.com/search/AdvPubForm.asp> by searching for "GC IQ Attachment".

- ☐ It is recommended to upgrade to the minimum firmware listed in the table using the GC Firmware Update Utility:

Instrument	Minimum Firmware Revision
6890N GC System	Firmware >= N.05.05 LAN assembly 04.7B3
6890Plus, 6890A	Firmware >= A.03.08
6850 GC serial# >= US10243001	Firmware >= A.05.04 LAN assembly 04.7B3
6850 GC serial# <= US00003200	Firmware >= A.03.03
6850 GC serial# <= US00003200 (held in controller 29A)	Firmware >= A.05.04
6850 GC serial# <= US00003200 (E)	Firmware >= E.01.02
Series II	Firmware >= A.03.02
D	Firmware >= A.06.00

The GC Firmware Update Utility is provided on the ChemStation 02.0x CD-ROM under the Support directory. Please check the Agilent Technologies website for the latest firmware: [http://www.chem.agilent.com/scripts/cag\\_firmware.asp](http://www.chem.agilent.com/scripts/cag_firmware.asp)

#### For CE systems only:

- ☐ If the firmware is not current, ask the customer to upgrade to the minimum firmware:  
Mainframe: 2.3  
DAD: 1.2

## Agilent ChemStation Software Modules

G2070BA/G2071BA/G2072BA/G2073BA/G2170BA/G2171BA/G2171BA/G2180BA/G2090BA/  
G2710BA/G1601BA/G2201BA



Agilent Technologies

### B.02.01 Upgrade Site Prep Checklist

#### ChemStation Solutions

Check for installed Add-On Solutions.

Before installing the Add-On solution, verify the correct revision of the Add-On Solution Products for ChemStation B.02.01 using the link to the LSM Marketing Homepage for the compatibility matrix/Product Support Plan:

[http://lsbu.marketing.agilent.com/article/ashow.asp?article\\_id=710](http://lsbu.marketing.agilent.com/article/ashow.asp?article_id=710)

#### Rev. A/Rev. B. Upgrades:

All Add-On Products need to be uninstalled BEFORE upgrading to B.02.01 ChemStation:

##### General:

- ☐ ChemStore
- ☐ ChemAccess
- ☐ ChemStation Plus Security F
- ☐ Other: \_\_\_\_\_

##### For LC, LC/MS systems only:

- ☐ Purify Software
- ☐ Active Splitter
- ☐ G1979A Multi-Signal Output Accessory (Side Box)
- ☐ Analyst
- ☐ Easy-Access
- ☐ Data Browser
- ☐ Other: \_\_\_\_\_

##### For GC systems only:

- ☐ Companion
- ☐ Retention Time Locking
- ☐ HeadSpace
- ☐ Other: \_\_\_\_\_

#### ChemStation System Customization

Check for customized solutions:

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shipped with the product  
or handed over by the  
Customer Engineer

macros due to the upgraded  
ChemStation structure point  
customer to the available  
documentation \*.

#### Additional Familiarization Upgrades from Rev. A to Rev. B ChemStation

- ☐ Explain the modified ChemStation structure (e.g. ChemStation.ini)
- ☐ Outline the new integrator features
- ☐ Outline the integrator changes and inform about the available documentation \*
- ☐ Outline the change for the “old” spectra tool and inform about the available documentation\*.

Detailed information regarding the integration/spectra update, macro changes etc. can be found in the Upgrade Preparation Guide for B.02.01 ChemStation, Publisher G2170-90226”.

### **3    Installation Qualification (IQ) Phase**

Installation Qualification

## **Installation Qualification**

## **Agilent 1200 Series Liquid Chromatograph Hardware and Software Installation Checklist**



## Hardware and Software Installation Checklist

### Hardware / Software Installation

**Purpose:** To ensure that instruments and systems are correctly installed and functioning as designed, in the customer's facility. Correct installation is the first step in ensuring that instruments and systems operate reliably over an extended lifetime.

#### Customer Responsibilities

The customer should ensure that the installation site is prepared in accordance with the specifications contained in the relevant system preparation document and that necessary operating supplies, consumables and usage documents such as vials, paper, etc. are available. A customer representative should be present all times during the installation.

**Note: Typical installation time is 1.5 hours for a system and 30 minutes for a module.**

If installation time was not sold for any section, check that section as not applicable.

### Installation Checklist

☐ Section NOT Applicable

#### Note:

If one section contains multiple choices for installed Hardware please encircle all modules that are part of the system and fill in the corresponding Serial Number.

#### Unpacking and inspection of shipped materials

**Note:** Shipping containers should not be opened until an Agilent Technologies representative is present

- ☐ Unpack all boxes and place equipment on bench. To prevent injury, get lifting assistance if needed.
- ☐ Retain shipping containers and material until installation is complete and performance is verified
- ☐ Notify order fulfillment of any

**Example Only:  
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or handed over by the  
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- ☐ When applicable, install computer system and connect all power interconnect cables
- ☐ Check for the Agilent LC Diagnostic CD-ROM and install this software component.

#### G1322A/79B– Degasser

☐ Section NOT Applicable

1. SN/FW# \_\_\_\_\_

2. SN/FW# \_\_\_\_\_

- ☐ Set up the degasser(s)
  - ☐ solvent inlet/outlet
- ☐ Priming each channel with Isopropanol from solvent bottle to pump inlet

#### G1310A/11A/12A – Pump

☐ Section NOT Applicable

FW# \_\_\_\_\_

FW# \_\_\_\_\_

FW# \_\_\_\_\_

- ☐ Set up the pump(s)
  - ☐ solvent inlet/outlet
  - ☐ waste drain
  - ☐ remote control (if used)
  - ☐ relay contacts (if installed)
  - ☐ seal wash tubing (if installed)
  - ☐ CAN
  - ☐ Agilent LAN (see note\*)
- ☐ Priming the pump
  - ☐ prepare solvents
  - ☐ turn on
  - ☐ purge
  - ☐ purge mobile phase
  - ☐ monitor the pressure

#### G1382A/G1376A Capillary Pump

#### G1379B Micro Degasser

#### G2225A/G2226A Nano pump

#### G1379B Micro Degasser

☐ Section NOT Applicable



## Hardware and Software Installation Checklist

1. SN/FW# \_\_\_\_\_

2. SN/FW# \_\_\_\_\_

- ☐ Set up the pump
  - solvent inlet/outlet
  - waste drain
  - remote control (if used)
  - relay contacts (if installed)
  - CAN
  - Agilent LAN (see note\*)
  - set up the degasser
  - solvent inlet/outlet
  - priming each channel with Isopropanol from solvent bottle to pump inlet
- ☐ Priming the pump
  - prepare solvents
  - turn on
  - purge
  - purge mobile phase
  - monitor the pressure

### G1361A – Prep. Pump

- ☐ Section NOT Applicable

1. SN/FW# \_\_\_\_\_

2. SN/FW# \_\_\_\_\_

- ☐ Set up the pump(s)
  - solvent inlet/outlet
  - waste drain
  - remote control (if used)
  - relay contacts (if installed)
  - seal wash tubing
  - CAN
  - Agilent LAN (see note\*)
- ☐ Priming a prep pump
  - Prime each pump individually
  - Use the syringe + adapter + tubing and connect to the waste outlet of the pump's EMPV
  - Turn ON the pump and

electronically switch the EMPV to waste

- Manually suck the solvent into and trough the pump
- Pump at least 0.5 liter of IPA through the pump

### G1328B – Manual Injector or 5065-9922 Prep. Manual Injector

- ☐ Section NOT Applicable

SN/FW# \_\_\_\_\_

- ☐ Setup the injector
  - start/stop cable to pump
  - base plate & mounting pole
  - position valve
  - inlet/outlet connected

**Example Only:**  
 See your originals shipped with the product or handed over by the Customer Engineer

- Agilent LAN (see note\*)

The following section applies if a **G1330B - ALS Thermostat** is installed together with any of the well-plate-, autosamplers or fraction collectors to generate a:

G1329A + G1330B - Thermostat. ALS

G1364B/C/D + G1330B Therm. Fraction Collector

G1367B + G1330B - Thermostat. High Performance Autosampler

G1377A + G1330B - Thermostat. Micro WPS

G2260A + G1330B - Thermostat. Preparative ALS

### 30B - ALS Thermostat Section NOT Applicable

SN/FW# \_\_\_\_\_

SN/FW# \_\_\_\_\_

SN/FW# \_\_\_\_\_

Setup the ALS Thermostat(s) underneath the module(s) that has (have) to be thermostatted.

**WARNING:** Do not connect the ALS thermostat cable while the line power is connected to the any of the modules. This would damage the sampler or fraction collector and the thermostat electronics.

- air channel adapter and plate
- ALS thermostat cable
- ALS thermostat waste drain

### G1316A - Column Compartment

- ☐ Section NOT Applicable

SN/FW# \_\_\_\_\_



## Hardware and Software Installation Checklist

- ☐ Setup the TCC
- ☐ solvent inlet/outlet
  - ☐ column
  - ☐ waste drain
  - ☐ remote control (if used)
  - ☐ CAN

### G1157A/58A/59A/60A/62A/63A

#### Valves

- ☐ Section NOT Applicable

1. SN/FW# \_\_\_\_\_

2. SN/FW# \_\_\_\_\_

3. SN/FW# \_\_\_\_\_

- ☐ Setup the Valves
- ☐ Setup the 1200 Series Valve
- ☐ solvent inlet/outlet
  - ☐ CAN
  - ☐ CAN-DC-In from other 1200 Module (e.g. G1367B Autosampler, G1364B/C/D Fraction Collector or G1361A Prep. Pump)

### G1383A Column Organizer

- ☐ Section NOT Applicable

SN/FW# \_\_\_\_\_

- ☐ Setup the column organizer
- ☐ base plate and organizer plate
  - ☐ rods
  - ☐ traverses
  - ☐ additional holders (if used)

### G1314B/C – VWD

- ☐ Section NOT Applicable

SN/FW# \_\_\_\_\_

- ☐ Set up the detector
- ☐ flow cell
  - ☐ solvent inlet/outlet

- ☐ waste drain
- ☐ remote control (if used)
- ☐ analog output (if used)
- ☐ relay contacts (if installed)
- ☐ CAN
- ☐ Agilent LAN (see note\*)

- ☐ Verify the operation of the detector

**Example Only:**  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

- ☐ Section NOT Applicable

1. SN/FW# \_\_\_\_\_

2. SN/FW# \_\_\_\_\_

- ☐ Set up the detector(s)
- ☐ deuterium lamp (if not installed)
  - ☐ solvent inlet/outlet
  - ☐ waste drain
  - ☐ remote control (if used)
  - ☐ analog output (if used)
  - ☐ relay contacts (if installed)
  - ☐ CAN
  - ☐ Agilent LAN (see note\*)
- ☐ Verify the operation of the detector

Lamp  
Intensity

1.
2.

Pass/Fail

WL  
calibration

1.
2.

Alpha  
Deviation

Beta  
Deviation

### G1321A – FLD

- ☐ Section NOT Applicable

SN/FW# \_\_\_\_\_

- ☐ Set up the detector
- ☐ solvent inlet/outlet
  - ☐ waste drain
  - ☐ remote control (if used)
  - ☐ analog output (if used)

CAN

Agilent LAN (see note\*)

the operation of the

or


Pass/Fail

Excitation  
Deviation

Emission  
Deviation

### G1362A – RID

- ☐ Section NOT Applicable

SN/FW# \_\_\_\_\_

- ☐ Set up the detector
- WARNING:** Make sure that all plugs are removed from the ports and the appropriate capillaries (inlet/outlet/recycling) are connected (maximum backpressure of 5 bar for flow cell).

- ☐ solvent inlet/outlet
- ☐ solvent recycle
- ☐ waste drain
- ☐ remote control (if used)
- ☐ analog output (if used)
- ☐ CAN
- ☐ Agilent LAN (see note\*)

- ☐ Verify the operation of the detector

Diode

Balance

--

Value



## Hardware and Software Installation Checklist

### G1364B/C/D – Fraction Collector

☐ Section NOT Applicable

1. SN/FW# \_\_\_\_\_

2. SN/FW# \_\_\_\_\_

3. SN/FW# \_\_\_\_\_

4. SN/FW# \_\_\_\_\_

☐ Setup the fraction collector(s)

- ☐ solvent inlet/outlet
- ☐ waste drain
- ☐ remote control
- ☐ relay contacts
- ☐ CAN
- ☐ Agilent LAN (optional)

Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

### G1390A – Universal Interface Box (UIB)

☐ Section NOT Applicable

SN/FW# \_\_\_\_\_

☐ Setup the universal interface box

- ☐ CAN
- ☐ Analog In (if used)
- ☐ GPIO / Analog In (if used)
- ☐ Relay Contacts (if used)

**Note: Agilent LAN connection is made between one (1) of the Agilent 1200 Series System modules and the Agilent ChemStation PC. If a detector is installed connect the LAN to this module.**



## Hardware and Software Installation Checklist

### G2408 Instant Pilot

#### ☐ Section NOT Applicable

SN/FW# \_\_\_\_\_

- ☐ Set up the control module
  - ☐ Connect via CAN to available instrument module

### Software Installation (Bundled)

#### ☐ Section NOT Applicable

Software Product: \_\_\_\_\_

Software Revision: \_\_\_\_\_

- ☐ Start Windows
- ☐ Start ChemStations Licenses and add the numbers. You find numbers in the 'Software Certificate and Registration Packet' envelopes.
- ☐ Configure TCP/IP if the instrument will be connected using LAN.
- ☐ If necessary install and Configure IO Libraries (LC/MS)
- ☐ If necessary install and configure Agilent Bootp Service for LAN connection.
- ☐ Use the Configuration Editor and configure your instruments.
- ☐ Install and Configure Software Add-Ons (if applicable)
- ☐ If present, install the PC Image software and create a backup using the Backup Solution User Guide as reference.
- ☐ If present, install the Agilent LC Diagnostic software.

### Software Installation (Un-Bundled)

#### ☐ Section NOT Applicable

Software Product: \_\_\_\_\_

Software Revision: \_\_\_\_\_

- ☐ Start Windows
- ☐ Install ChemStation using the ChemStation Installation guide for reference.
- ☐ Check if a printer driver is

**Example Only:**  
 See your originals  
 shipped with the product  
 or handed over by the  
 Customer Engineer

- ☐ configure AGILENT Bootp Service if the instrument will be connected using LAN
- ☐ Use the Configuration Editor and configure your instruments.
- ☐ Install the Agilent LC Diagnostic software.

### 1200 LC Checkout

- ☐ Start a run
  - ☐ Prepare:
    1. pump(s)
    2. online degasser (s) (if present)
    3. injection device(s)
    4. column compartment
    5. detector(s)
    6. fraction collector(s) (if present)
    7. Valve(s) (if present)
    8. recording device
  - ☐ Attach results to installation documentation
- Fill out instrument logbook  
 Verify connection to the Agilent LC Diagnostic Tool.



## Hardware and Software Installation Checklist

### **Service Review**

- ☐ Affix any reports generated to this Checklist
- ☐ Record in the instrument logbook date and time install was completed
- ☐ Explain Agilent warranty for Hardware, Software and return policy for the Instrument Service Center
- ☐ Explain how to log an instrument service call
- ☐ Explain support services
- ☐ Explain how to use the instrument
- ☐ Advise customer of training options
- ☐ Advise the customer of following useful Agilent sites:

e.g. 1200 Series Firmware  
(Downloads/patches)

#### **Exclusive offers:**

[www.agilent.com/chem/exclusiveoffers](http://www.agilent.com/chem/exclusiveoffers)

#### **Library -**

<http://www.agilent.com/chem/library>

#### **Education -**

[www.agilent.com/chem/education](http://www.agilent.com/chem/education)

#### **eSeminars -**

[www.agilent.com/chem/eseminars](http://www.agilent.com/chem/eseminars)

#### **Software Status Bulletins and Patches -**

[www.agilent.com/chem/techsupport](http://www.agilent.com/chem/techsupport)

Supplies - [www.agilent.com/chem/supplies](http://www.agilent.com/chem/supplies)

#### **Tech Support -**

[www.agilent.com/chem/techsupport](http://www.agilent.com/chem/techsupport)

**Note:** Password is the Registration number for the software

☐ Sales Order Number

\_\_\_\_\_

☐ Service Order (SO) Number

\_\_\_\_\_

☐ Date completed

\_\_\_\_\_

☐ Customer Signature

**Example Only:**  
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or handed over by the  
Customer Engineer

### **3    Installation Qualification (IQ) Phase**

#### **Installation Qualification**

## **Agilent LC and CE ChemStation Software G2170BA, G2171BA, G2175BA, G2180BA, G2185BA, G211601BA, G2172BA, G2205BA Software Installation Checklist B.02.0x**



## Software Installation Checklist B.02.0x

### Purpose of Installation

To ensure that instruments and systems are correctly installed and functioning as designed, in the customer's facility. Correct installation is the first step in ensuring that instruments and systems operate reliably over an extended lifetime.

### Customer Responsibilities

The customer should ensure that the installation site is prepared in accordance with the specifications contained in the site preparation installation manual and that necessary operating supplies, consumables and usage dependent items such as paper, pens, etc. are available. A customer representative should be present at all times during the installation.

### 1. Installation Checklist generic

- ☐ Unpack and verify condition and completeness of shipment.
- ☐ Check license numbers and fill in installation documentation S/N fields if necessary. You find these numbers in the 'Software Certificate and Registration Packet' envelopes.  
**Note:** The license registration numbers consist of 10

**Example Only:**  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

### Bundle system (if applicable)

- ☐ Start Windows
- ☐ Start ChemStation -> Add Licenses and add the license numbers. You find these numbers in the 'Software Certificate and Registration Packet' envelopes.
- ☐ Install the Agilent BootP Service program if the instrument (if necessary ) for LAN connection or
- ☐ Install the IO libraries if the instrument will be connected using GP-IB
- ☐ Use the Configuration Editor and configure your instruments.
- ☐ Install Agilent LC Diagnostic Tool

### 2b. Installation Checklist

#### Non-Bundle system (if applicable)

- ☐ Install the IO libraries if the instrument will be connected using GP-IB or
- ☐ Install the Agilent BootP Service program (if necessary ) for LAN communication
- ☐ Start the ChemStation installation by starting setup.exe from the Agilent ChemStation CD-ROM.  
**Note:** A previously installed ChemStation will be updated.
- ☐ Choose the installation directory. The default is C:\CHEM32.
- ☐ Select the instrument number to be installed, the desired software for this instrument and type in the license number.

- ☐ If you need to install more than one instrument, repeat the preceding step.
- ☐ Use the Configuration Editor and configure your instruments.
- ☐ Install Agilent LC Diagnostic Tool
- ☐ Close all Windows applications, close Windows and restart the computer.



**Software Installation Checklist B.02.0x**

**3. Installation Checklist generic**

- ☐ Start ChemStation -> Installation Qualification to ensure correct installation.
- ☐ If there is an online instrument, start the appropriate Online Instrument ChemStation.
- ☐ If there is no online instrument, start the appropriate Offline Instrument ChemStation.
- ☐ Start the Agilent LC/CE Tool and verify connection.

**4. If Familiarization is performed:**

- ☐ Explain how to use the software (refer customer to online maintenance section for sample methods and data files installed with the software).
- ☐ Explain Agilent Support services and how to obtain help, note if customer requires further information.

**Example Only:**  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

## Familiarization Checklist

## **Agilent 1200 Series Liquid Chromatograph Familiarization Checklist**



## Familiarization Checklist

### Hardware / Software Familiarization

#### Purpose of Procedure

To demonstrate the steps required to perform a basic analysis using a standard sample or internal data file, evaluate the resulting data and perform routine operational maintenance.

Familiarization is intended to give operators a basic overview of the operation and maintenance of new instruments, systems and applications software and is not designed to substitute for a full operator training course.

#### Customer Responsibilities

The customer should ensure that necessary operating supplies, consumables and usage dependent items such as vials, syringes and solvents are available. User manuals for the instrument should be present at all times during the familiarization, otherwise important information on operation and maintenance may be missed. The manuals delivered with the instrument will be used as a guide during familiarization and should be available.

**Note: Typical familiarization times for a Bundled LC System are:**

**2D System –approx. 6.5 Hours**

**3D System – approx. 8.5 Hours**

**If customer did not purchase familiarization time for the 1200, check that section as not applicable.**

### Hardware Familiarization

#### ☐ Section Not Applicable

#### System Overview and Hardware Familiarization

- ☐ Power on each module and describe the various states of the status indicators.
- ☐ Indicate the installed modules in the following list that will be covered as part of the familiarization:-

**Example Only:  
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or handed over by the  
Customer Engineer**

- ☐ G1316A - Column Compartment
- ☐ G1157A/58A/59A/60A/62A/63A – Valves
- ☐ G1314B/C – VWD
- ☐ G1315B/C–DAD / G1365B/C–MWD
- ☐ G1321A – FLD
- ☐ G1362A – RID
- ☐ G1364B/C/D – Fraction Collectors
- ☐ G1330B – Thermostat for Samplers or Fraction Collectors
- ☐ **Below Item Not Applicable**  
(see note\*)
- ☐ Demonstrate stand-alone operation for each installed Module using the Control Module. Use the “Control

Module Screens for the 1200” section from the appropriate Module Reference Manual as guidance. Review the following Screens:

1. Views
2. Diagnostics and Tests Screen

#### Maintenance/Diagnostics

- ☐ Review common maintenance procedures by reviewing the “Simple Repairs” section in the appropriate Reference Manual

**For Systems that do not have Control Module, detailed familiarization of the 1200 set points will be covered in the DIT METHOD and AGNOSTIC portions of the Software Familiarization.**



## Familiarization Checklist

### Software Familiarization

#### ☐ Section Not Applicable

#### System Startup

- ☐ Demonstrate switching on instruments, PC and peripherals
- ☐ Demonstrate starting Windows operating system, logon password
- ☐ Demonstrate starting LC ChemStation software
- ☐ Describe ChemStation Configuration Editor
- ☐ Describe Online and Offline session

#### General Familiarization

- ☐ Describe software main menu
- ☐ Demonstrate Online Help Tutorial
- ☐ Demonstrate the ChemStation layout
- ☐ Explain use of the various Views and the usage of the Navigation Pane
- ☐ Explain ChemStation Explorer
- ☐ Explain Packaging Concept of ChemStation Data
- ☐ Demonstrate mouse actions in the various tables and graphic items
- ☐ Explain Full/Short menu and view structures
- ☐ Explain the user access levels

#### Configure Instruments

- Where necessary (e.g. for samplers and fraction collectors: used trays and vessels)
- ☐ Configure wellplates and test tubes (if applicable)

For fraction collectors, only:

- ☐ Configure delay volume,

collection order and mode,  
needle movement

#### Edit Method

- ☐ Prepare a method using the “Edit Entire Method” menu item to analyze the checkout sample
- ☐ Don’t forget to explain parameters under the “More and Auxiliary”- Buttons or Menus
- ☐ **If the Spectral Software (G2180BA) is loaded, select acquisition of all spectra**
- ☐ Save the method as ISO\_1.M
- ☐ Explain the difference between

**Example Only:**  
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shipped with the product  
or handed over by the  
Customer Engineer

- ☐ Demonstrate status monitors and on-line signal display

#### Edit Sequence

- ☐ Load sequence DEF\_LC.S
- ☐ Explain usage of the sequence preferences
- ☐ Explain how to create sequence templates and demonstrate the data storage based on this definition
- ☐ Demonstrate preparation of a sequence using the “Sequence Parameters” and “Sequence Table” menus
- ☐ Run a single injection sequence using the checkout sample.
- ☐ Demonstrate “Partial sequence” and “Sequence Save”

#### Data Analysis

- ☐ Demonstrate use of the navigation pane
- ☐ Explain navigation table and demonstrate table options
- ☐ Demonstrate the various ways to load a signal and how to get signal specific information
- ☐ Load data file ISOCRA.D found in X:\CHEM32\1\DATA\DEMO\...
- ☐ Manipulate graphics windows (Zoom, print window, etc.)
- ☐ Integrate signal (Automated and Manual)
- ☐ Setup report using “Specify report” menu
- ☐ Print an area percent report
- ☐ Demonstrate “reviewing” and “reprocessing” of data files using the navigation table in Data Analysis

#### Calibration

- ☐ Load method DEF\_LC.M
- ☐ Load data file ISOCRA.D
- ☐ Demonstrate the steps in creating a single level calibration
- ☐ Demonstrate generating a External Standards report

#### Spectral Data Evaluation

- ☐ **Section Not Applicable**
- ☐ Demonstrate display of spectra and reference spectra
- ☐ Demonstrate display of a 3D plot
- ☐ Demonstrate display of an Iso-absorbance plot
- ☐ Demonstrate the creation of a Spectral Library
- ☐ Demonstrate creation of an Automated Library Search Report



## Familiarization Checklist

- ☐ Demonstrate Peak Purity

### Purification and Fraction Collection

- ☐ **Section Not Applicable**

- ☐ Demonstrate, how to reset the tray fill information
- ☐ Demonstrate, how to perform a delay calibration
- ☐ Demonstrate fraction collection in the time based and peak based mode
- ☐ Demonstrate the use of the Fraction Preview
- ☐ Demonstrate the Fraction collection in a single (method) using the “S Info” for specifying a Start Location
- ☐ Generate and run a Fraction Collection Sequence
- ☐ Demonstrate the use of the Fraction Start position Sequence Parameters Sequence Table
- ☐ Demonstrate, how to do Sample Recovery (if applicable, appropriate trays and configuration must be available)
- ☐ Demonstrate, how to generate a report including Fraction Tickmarks and Fraction Table

### Maintenance/Diagnostics

- ☐ Introduce the diagnostic tools in ChemStation and Agilent LC Diagnostic
- ☐ Describe EMF Utilities and how to set limits in ChemStation /Agilent LC Diagnostic
- ☐ Demonstrate troubleshooting using diagnostics in ChemStation / Agilent LC

### Diagnostic

- ☐ Explain file management and other software utilities
- ☐ Describe the importance of data back-up, disk checks, disk defragmentation, archiving and master disk storage
- ☐ Discuss the importance of disabling power management options and utilities that run automatically
- ☐ In Agilent LC Diagnostic describe Status Report and how to edit a report as PDF or as printable file
- ☐ In Agilent LC Diagnostic

**Example Only:**  
**See your originals**  
**shipped with the product**  
**or handed over by the**  
**Customer Engineer**

- ☐ logbook date and time install was completed
- ☐ Explain Agilent warranty for Hardware, Software and return policy for the Instrument Service Center
- ☐ Explain how to log an instrument service call
- ☐ Explain support services
- ☐ Explain how to use manuals
- ☐ Advise customer of additional training options
- ☐ Give the customer a tour of the following useful Agilent web sites:

### Technical Support

[http://www.chem.agilent.com/Scripts/cag\\_techsupport.asp](http://www.chem.agilent.com/Scripts/cag_techsupport.asp)

### e.g. 1200 Series Firmware (Downloads/patches)

#### Library

<http://www.chem.agilent.com/Scripts/Library.asp>

#### Education

[http://www.chem.agilent.com/Scripts/cag\\_countrysites.asp?pf=T](http://www.chem.agilent.com/Scripts/cag_countrysites.asp?pf=T)

#### E-seminars

<http://webshop.chem.agilent.com/iccdocs/seminarList.shtml>

#### Supplies

<http://www.chem.agilent.com/Scripts/Sp?lPage=572>

#### Agilent Status Bulletins and Patches

[http://www.chem.agilent.com/scripts/cag\\_techreg.asp](http://www.chem.agilent.com/scripts/cag_techreg.asp)

Registration Password is the Registration Number for the software

Agilent Sales Order Number

- ☐ Service Order (SO) Number

- ☐ Date completed

- ☐ Customer Signature

- ☐ Support Provider Signature

## **Agilent 1200 Series Liquid Chromatograph Scorp of Work Installation and Famliarization**

**3    Installation Qualification (IQ) Phase**  
Declaration of Conformity and System Validation

## **Declaration of Conformity and System Validation**

## **Declaration of Conformity According to ISO/IEC Guide 22 and CEN/CENELEC EN 45014**



**Agilent Technologies**

**DECLARATION OF CONFORMITY**  
According to ISO/IEC Guide 22 and CEN/CENELEC EN 45014



**Manufacturer's Name:** Agilent Technologies International sarl  
**Manufacturer's Address:** Rue de la Gare 29  
**Supplier's Address:** CH – 1110 Morges  
Switzerland

**Declares under sole responsibility that the product as originally delivered**

**Product Name:** 1200 Series Isocratic Pump, 1200 Series Quaternary Pump

**Model Number:** G1310A, G1311A

**Product Options:** This declaration covers all options of the above products

**complies with the essential requirements of the following applicable European Directives, and carries the CE marking accordingly:**

Low Voltage Directive 73/23/EEC, amended by 93/68/EEC  
EMC Directive 89/336/EEC, amended by 93/68/EEC

**and conforms with the following product standards:**

**EMC**

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or handed over by the  
Customer Engineer**

**mit**

Group 1 Class B  
Group 1 Class A<sup>[1]</sup>

1 kV CD, 8kV AD  
10 V/m, 80-1000 MHz  
5kV signal lines, 1kV power lines  
5 kV line-line, 1 kV line-ground  
100 V, 0.15-80 MHz  
1 cycle (20ms), 100%

Australia/New Zealand: AS/NZS 2064.1  
Canada ICES / NMB-001:1998

The product was tested in a typical configuration with Agilent Technologies test systems.  
<sup>[1]</sup> 1200 Series module with LAN Communication Interface attached.

**Safety**

IEC 61010-1:2001 / EN 61010-1:2001  
Canada: CSA C22.2 No. 1010.1:1992+A2:1997  
USA: UL3101.1

**Supplementary Information:**

This ISM device complies with Canadian ICES-001. Cet appareil ISM est conforme à la norme NMB-001 du Canada.

**This DoC applies to above-listed products placed on the EU market after:**

December 19, 2005

Date

Wolfgang Wilde, Quality Manager

For further information, please contact your local Agilent Technologies sales office, agent or distributor,  
or Agilent Technologies Deutschland GmbH, Herrenberger Straße 130, D 71034 Böblingen, Germany.



**3 Installation Qualification (IQ) Phase**  
Declaration of Conformity and System Validation

**Declaration of Conformity to manufacturing Specifications**



**Agilent Technologies**

## **Declaration of Conformity**

to manufacturing specifications

We herewith inform you that the product  
G1311A with serial number:

**DE60555268**

has successfully passed all our production  
quality tests.

During final instrument performance verification  
the following functional characteristics were

**Example Only:  
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or handed over by the  
Customer Engineer**

**Operational Test**



February 20, 2006

Signature: \_\_\_\_\_

Test Technician: Sven Buggermann

**G1311A**



**DE60555268**



## ChemStation Declaration of System Validation



## Declaration of System Validation

We herewith inform you that the software product/system

Product Name	Product Number	Revision Number
ChemStation for GC	G2070BA, G2071BA, G2075BA, G2090BA	B.02.0x (where x ranges from 0 to 9)
ChemStation for LC	G2170BA, 2171BA, G2175BA,	B.02.0x (where x ranges from 0 to 9)
ChemStation		(where x ranges from 0 to 9)
ChemStation		(where x ranges from 0 to 9)
ChemStation		(where x ranges from 0 to 9)
ChemStation		(where x ranges from 0 to 9)
Software Rev.		ole

Example Only:  
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shipped with the product  
or handed over by the  
Customer Engineer

was developed according to the quality process and software life cycle followed by the Life Sciences and Chemical Analysis divisions of Agilent Technologies. Life cycle check-point details were reviewed and approved by management. The product was found to meet its functional and performance specifications, and release criteria at release to shipment.

In order to fulfill the validation requirements of the users of this product according to current regulations and quality standards including, but not limited to, 21 CFR 210 (Good Manufacturing Practice for Drugs), 21 CFR 211 (current Good Manufacturing Practice for finished pharmaceuticals), 21 CFR 58 (Good Laboratory Practice), Agilent Technologies will make the source code and the documents referenced on page 2 of this declaration available to an authorized governmental or regulatory agency for inspection at its Pharmaceutical Solutions Unit, Waldbronn, Germany (terms and conditions to be negotiated).

Agilent Technologies will maintain possession of all documents and their reproductions and may require a confidential disclosure agreement to be provided by those requiring access to these documents.

Date:

February 2006

Engineering manager:

Ulrich Wiedenrodt  
(PHS)

Shangyan Kane  
(CAS)

Quality manager:

G. G. G. G.  
(PHS)

Nancy J. Adams  
(CAS)

**Product description**

Specifications

**Lifecycle Phase Transition Approvals**

Proposal

Investigation

Design

Implementation

Test

Manufacturing Release

**Software Quality Assurance**

Quality Plan



**Example Only:**  
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Change Management Process

Coding Standards

**Source Code**

G2170-90523

Part Number: **G2170-90523**

Edition 02 / 2006  
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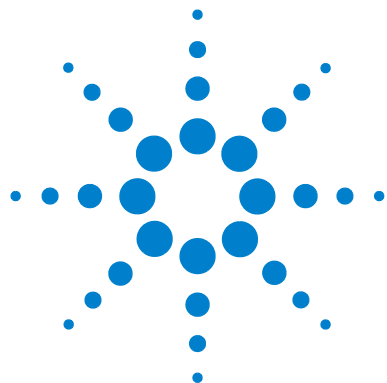
Agilent Technologies  
Hewlett-Packard-Strasse 8  
76337 Waldbronn, Germany

## **ChemStation Installation Verification Report**

# ChemStation Installation Verification Report

ChemStation Installation Verification		
File Help		
File	Version	FileDescription
Identical files		
hpsched.exe	32.3.0.2	Agilent ChemStation Scheduler
msstatus.ini		(Initialization)
startm.exe	32.2.1.0	StartM
apg_top.exe	32.2.2.0	CAG Server executable
apgdde.dll	32.3.1.0	Analytical Product Group DDE Library
commtask.exe	32.2.1.0	CAG COM port connection process
hp-lc.ini		(Initialization)
hp-ms.ini		(Initialization)
hpce.ini		(Initialization)
hpced02.exe	32.3.7.0	APG Configuration Editor
hpfabs00.dll	32.3.1.0	support functions
hpgc.ini		(Initialization)
hpgthk00.dll	32.2.1.0	Generic Thunk Module
hpnls01.dll	32.3.1.0	NLS Dynamic Link Library
hpted_01.dll	32.2.1.0	Table Editor Control Dynamic Link Library
hputi02.dll	32.3.2.0	Agilent Utility Library
hsiclsk.exe	32.3.1.0	APG DataComm Server
iapg.dll	32.2.1.0	CAG Server interface
iwacos.dll	32.2.1.0	CAG Server interface
larpalan.dll	32.2.1.0	CAG LAN Server link dll
lhpbisicl.dll	32.2.2.0	CAG DataComm Server
licop.ini		(Initialization)
lrs232.dll	32.3.1.0	HP-APG DataComm Server
mfc71.dll		
mfc71u.dll		
msvcp71.dll		
msvc71.dll		
papg.dll		
plcop.dll		
pwacos.dll		
pwacos32.dll		
res_mgr.dll		
server.dll		
setup.dll		
sockettask.exe		
core\la_epc.mcx		
core\agilent.chemstation.ui.dialogs.preferences.c		
core\agilent.chemstation.ui.navigationbar.dll		
core\agilent.chemstation.ui.toolbars.dll		
core\agilent.chemstation.ui.navigationtable.dll		
core\bspproxilib.dll		
core\coreconf.reg		
core\cstools.exe		
core\cstools.ini		
core\chemmain.exe		
core\chemmainremoting.dll	0.0.1.6	
core\cppproxilib.dll	0.0.1.15	
core\vggureg.reg		(Register)
core\devexpress.data3.dll	3.2.4.0	
core\devexpress.utils3.dll	3.2.4.0	
core\devexpress.xtrabars3.dll	3.7.4.0	
core\devexpress.xtraeditors3.dll	3.2.4.0	
core\devexpress.xtragrid3.dll	3.2.4.0	
core\devexpress.xtranavbar3.dll	2.7.4.0	
Installation Verification completed successfully.		

## Customer contributed documents



## 4

# Operational Qualification (OQ) Phase

OQ/PV Protocols

Agilent ChemStation Verification Test Report

Certificates showing traceability of:

Standard: Caffeine Kit

Holmium Oxid Glass Filter (Type Hoya HY-1)

Customer contributed material

For the items marked with a \* example pages are added. It is the responsibility of the user to replace these with the originals. Documents for calibrated test equipment are handcarried by the Agilent Technologies customer engineer who performs for example the OQ/PV procedure. Copies of these documents should be added to the present binder. The user should feel free to add further documents, e.g. not supplied by Agilent Technologies whenever he thinks this is appropriate.



## **OQ/PV Protocols**

- Agilent 1200 Series modules
- Agilent ChemStation Plus

Add here the protocols as handed over by a certified Agilent service engineer after an Operational Qualification (OQ).

Recommended times for OQ

- Installing hardware or software
- Repairing a mayor piece of hardware
- Any software change that affect system security, data integrity or administrative controls

# Agilent ChemStation Verification Test Report

=====

ChemStation Verification Test Report

=====

Tested Configuration :

Component	Revision
ChemStation for LC 3D systems	Rev. B.02.01 [241]
Microsoft Windows	Microsoft Windows 2000
Processor	Intel Pentium Pro
CoProcessor	yes

ChemStation Verification Test Details :

Test Name : C:\CHEM32\1\VERIFY\LCAREA.VAL  
Data File : C:\CHEM32\1\VERIFY\LCAREA.DAT  
Method : C:\CHEM32\1\VERIFY\LCAREA.METHOD  
Original Datafile  
Original Aquisition Method  
Original Operator  
Original Injection Date  
Original Sample Name

Signals Tested :  
Signal 1 : ADC1 A, ADC1 B

**Example Only:**  
**See your originals**  
**shipped with the product**  
**or handed over by the**  
**Customer Engineer**

ChemStation Verification Test Results :

Test Module	Selected For Test	Test Result
Digital electronics test	No	N/A
Integration test	Yes	Pass
Quantification test	Yes	Pass
Print Analytical Report	Yes	N/A

ChemStation Verification Test Overall Results : Pass

#### **4    Operational Qualification (OQ) Phase**

Certificates showing traceability of:

**Certificates showing traceability of:**

## **Standard: Caffeine Kit**

# Certificate of Analysis

## Caffeine Standards Kit

**Part No** 8500-6762

**Lot No** OC367446

**Concentrations:**

Caffeine in water:

Nominal value	Effective value determined by UV-spectroscopy using the absorption maximum at 273 nm
500 µg/L	499.9 µg/L ± 0.5%
1000 µg/L	1000.0 µg/L ± 0.5%
1500 µg/L	1500.0 µg/L ± 0.5%
2000 µg/L	2000.0 µg/L ± 0.5%
2500 µg/L	2500.0 µg/L ± 0.5%
3000 µg/L	3000.0 µg/L ± 0.5%
3500 µg/L	3500.0 µg/L ± 0.5%
4000 µg/L	4000.0 µg/L ± 0.5%
4500 µg/L	4500.0 µg/L ± 0.5%
5000 µg/L	5000.0 µg/L ± 0.5%

**Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer**

**Purity grades:**

Caffeine:

Concentration (acid. titration): 98.5 – 101.5 %

Heavy metals (as Pb): < 0.001%

Loss on drying (105°C): < 0.5%

Water:

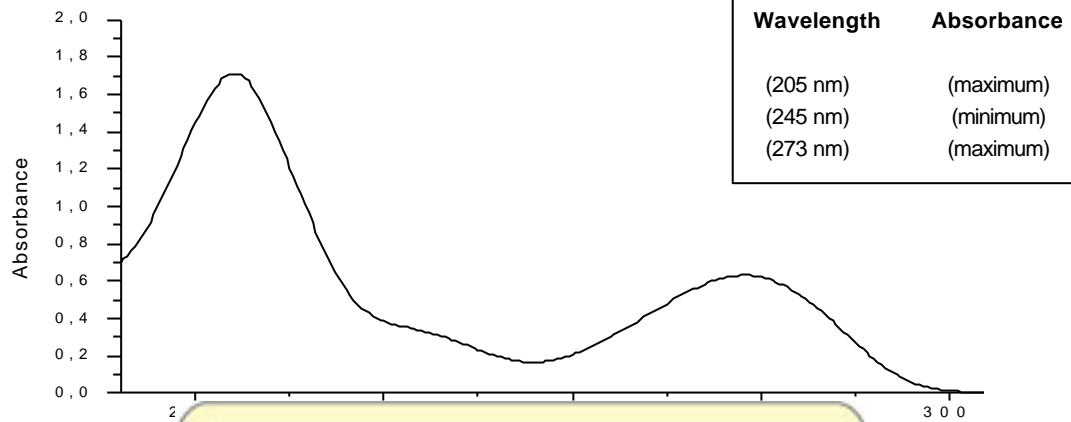
18.2 MO x cm

The standards in this kit have been produced gravimetrically using ISO 9000 quality procedures. Balances used are calibrated regularly against PTB (Physikalisch Technische Bundesanstalt [Federal Physical-Technical Institute] – Braunschweig – Germany) traceable weight sets.

The standards have been analysed on a high-performance UV/VIS/NIR spectrophotometer. The spectrophotometer is regularly validated for accuracy and reproducibility of absorbance and wavelength as well as for linearity, baseline drift, stray light and spectral resolution power using the following testing materials:

Absorbance:	NIST SRM 1930 and double aperture method
Wavelength:	NIST SRM 2034, emission lines of D <sub>2</sub> -, Hg- and Ar-lamps
Stray light:	NIST SRM 2032
Spectral resolution power:	Half width value of D2 emission lines for checking the effective optical bandwidth

**UV/VIS Spectrum** Caffeine in water [concentration: 125 µg/ml]



**Date of release:**

**Expiration date:**

Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

J. Gernand  
Product manager

#### **4    Operational Qualification (OQ) Phase**

Certificates showing traceability of:

### **Holmium Oxid Glass Filter (Type Hoya HY-1)**

## Declaration of Conformity

We herewith inform you that the

### **Holmium Oxide Glass Filter (Type Hoya HY-1)** (Part No. 79880-22711)

meets the following specification of absorbance maxima positions:

Product Number	Series	Measured Wavelength *	Wavelength Accuracy	Optical Bandwidth
79883A	1090	361.0 nm	+/- 1 nm	2 nm
79854A	1050	418.9 nm		
G1306A	1050	Example Only: See your originals shipped with the product or handed over by the Customer Engineer		6 nm
G1315A	1100			
G1315B/C	1100			
G1600				
79853C	1050			
G1314A/B/C	1100			6 nm

\*) The variation in Measured wavelength depends on the different Optical Bandwidth.

Agilent Technologies guarantees the traceability of the specified absorbance maxima to a National Institute of Standards & Technology (NIST) Holmium Oxide Solution Standard with a lot-to-lot tolerance of  $\pm 0.3$  nm.

The wavelength calibration filter built into the Agilent Technologies UV-VIS detectors is made of this material and meets these specifications. It is, therefore, suitable for wavelength calibration of these detectors within the specified wavelength accuracy of the respective detector over its wavelength range.

January 13, 2006

-----  
(Date)

*Thomas Jor*

-----  
(Engineering Manager)

*G. Gable*

-----  
(Quality Manager)

P/N 89550-90501



Revision: E  
Effective by: Jan 13, 2006



**Agilent Technologies**

## Customer contributed material

## 4 Operational Qualification (OQ) Phase

Customer contributed material



## 5 Performance Qualification (PQ) Phase

### Preventive Maintenance Checklist

Agilent 1200 Series Liquid Chromatograph Preventive Maintenance Checklist

Agilent 1200 Series Liquid Chromatograph Scope of Work Preventive Maintenance

Agilent 1100/1200 Series LC/MSD Quad Major Preventive Maintenance Checklist

Agilent 1100/1200 Series LC/MSD Quad Major Interim Preventive Maintenance Checklist

System performance and noise

Customer contributed material

For the items marked with a \* example pages are added. It is the responsibility of the user to replace these with the originals. The user should feel free to add further documents, e.g. not supplied by Agilent Technologies whenever he thinks this is appropriate.



## **Preventive Maintenance Checklist**

## Agilent 1200 Series Liquid Chromatograph Preventive Maintenance Checklist



## Preventive Maintenance Checklist

### Purpose of Procedure

Preventive Maintenance is an Agilent Technologies recommended procedure designed to reduce the likelihood of electro-mechanical failures. Failure to perform preventive maintenance may reduce the long-term reliability of certain instruments and systems.

### Customer Responsibilities

Customers should ensure that all necessary operating supplies, consumables and usage dependent items such as paper, pens, solvents (HPLC grade water, 2-propanol) are available. Analytical columns should be removed from the column compartment, the system should be flushed with HPLC grade water and all samples removed from the autosampler. A Customer Representative should be available while performing the preventive maintenance procedure.

### LC System

**Note – Complete the PM Checklist in the order given.**

- ☐ Ask Customers if they would like the module(s) firmware updated. If firmware is to be updated, the Firmware IQ attachment form must be filled out and appended to the instrument IQ.

**Firmware Updated?** \_\_\_\_\_ **YES**  
 \_\_\_\_\_ **NO**

- ☐ Check instrument logbook and exclude maintenance on recently serviced items.
- ☐ Perform general inspection of each LC module.
- ☐ Check that each waste tray and interface is properly mounted.

- ☐ Check for proper mounting and functionality of all leak sensors.
- ☐ Wash deposits from each leak sensor.

## PUMPS

### G1310A/11A/12A – Pump

- ☐ **1. Record model number**

**Example Only:**  
**See your originals**  
**shipped with the product**  
**or handed over by the**  
**Customer Engineer**

- ☐ **3. Record model number**

- ☐ **3. Record serial number**

- ☐ Remove and disassemble pump head(s).
- ☐ Remove and clean plungers.
- ☐ Clean support rings.
- ☐ Remove old seals, clean piston chambers, and replace seals.
- ☐ If the seal wash option is installed, remove and replace wash seals and gaskets. Replace the seal wash pump cassette, if the NEW active seal wash is installed.
- ☐ Reassemble pump-head(s) and install on metering drive.
- ☐ Perform seal wear-in procedure for standard seals **ONLY**.

- ☐ Replace PTFE Frit, gold seal, and plastic cap in purge valve.
- ☐ Replace the sieve, gold seal, and plastic cap in the outlet ball valve (2x for G1312A).
- ☐ Open purge valve and attach restriction capillary to purge valve. Prime applicable channel into a suitable container with IPA for 10 minutes. For a Binary pump, prime Channel A. For a Binary pump with a solvent selection valve, prime Channel A2. For a Quaternary pump, prime Channel 1. While purging, begin maintenance on the sampler (or manual injection valve) and Column Compartment if installed. Perform built-in leak test.

3. Result


Pass/Fail

Pass/Fail

Pass/Fail

### G1376A Capillary Pump G2226A Nano Pump

- ☐ **Record serial number**

- ☐ Remove and disassemble pump heads.
- ☐ Remove and clean plungers.
- ☐ Clean support rings.
- ☐ Remove old seals, clean piston chambers, and replace seals.
- ☐ Reassemble pump-heads and install on metering drive.
- ☐ Go to the “Normal Mode” and perform a seal wear-in procedure for standard seals **ONLY**.
- ☐ Replace PTFE Frit, gold seal, and plastic cap in purge valve (**if the**



**Preventive Maintenance Checklist**

- pump is used in Normal Mode)**
- ☐ Replace the sieve, gold seal, and plastic cap in the outlet ball valve (2x).
  - ☐ Change the frit located in the filter in front of the EMPV.
  - ☐ Perform the EMPV test procedure.

Result  Pass/Fail

- ☐ Perform built-in pressure test.

Result  Pass/Fail

- If the system is used in micro mode, perform the “Micro pressure test”:

Pressure value	<input type="text"/>	Pass/Fail
Flow	<input type="text"/>	Pass/Fail

- If the system is used in normal mode, perform the “Normal mode pressure test”:

Slope of Pressure ramp	<input type="text"/>	Pass/Fail
Pressure value	<input type="text"/>	Pass/Fail
Final Pressure drop	<input type="text"/>	Pass/Fail

**G1361A Preparative Pump**

For a binary setup perform these steps for both pumps

- ☐ 1. Record serial number.

\_\_\_\_\_

- ☐ 2. Record serial number.

\_\_\_\_\_

- ☐ Remove and disassemble pump head.
- ☐ Remove and clean plungers.
- ☐ Clean support rings.
- ☐ Remove old seals, clean piston chambers, and replace seals.
- ☐ Reassemble pump-head and install on metering drive.
- ☐ Replace the filter cup in the Multi Assy.
- ☐ Pump 200 ml of IPA through the pump.
- ☐ Replace the SST filter assembly.
- ☐ Replace the seal wash pump cartridge and tubings.
- ☐ Perform the EMPV cleaning

**Example Only:**  
 See your originals  
 shipped with the product  
 or handed over by the  
 Customer Engineer

1. Result  Pass/Fail

2. Result  Pass/Fail

**SAMPLERS**

**G1329A - Autosampler**  
**G2260A Prep. Autosampler**

- ☐ 1. Record model number

\_\_\_\_\_

- ☐ 1. Record serial number

\_\_\_\_\_

- ☐ 2. Record model number

\_\_\_\_\_

- ☐ 2. Record serial number

- ☐ Replace rotor seal.
- ☐ Replace the needle and the needle seat assembly.
- ☐ Clean the transport unit rods, using a lint free cloth and IPA. DON'T use any lubricant for the transport unit rods!
- ☐ Check that the ALS Thermostat unit drain tube is positioned correctly (if applicable).
- ☐ Purge Autosampler and Column Compartment with IPA for 5 minutes.
- ☐ If the Column Compartment contains a Column Switching Valve, Cap outlet of ALS with blank nut. Otherwise, Cap outlet of Column Compartment with blank nut.
- ☐ Perform built-in pressure test

t  Pass/Fail

2. Result  Pass/Fail

**G1328B Manual Injector**  
**5065-9922 Prep. Manual Injector**

- ☐ 1. Record model number

\_\_\_\_\_

- ☐ 1. Record serial number

\_\_\_\_\_

- ☐ Replace rotor seal.
- ☐ Purge Injector and Column Compartment with IPA for 5 minutes.
- ☐ If the Column Compartment contains a Column Switching Valve, Cap outlet of Injector with blank nut. Otherwise, Cap outlet of Column Compartment with



**Preventive Maintenance Checklist**

blanking nut.  
☐ Perform built-in pressure test  
 Result  Pass/Fail

**G1367B High Performance Autosampler**

**G1377A Micro Well Pl. Sampler**  
**G2258A Dual Loop Autosampler**

☐ 1. Record model number

☐ 1. Record serial number

☐ 2. Record model number

☐ 2. Record serial number

- ☐ Replace rotor seal.
- ☐ Replace the needle and the needle seat assembly (for all samplers except for the G2258A DLA. For the DLA, this only has to be performed, if the needle is bent or needle/needle seat are leaky. Must be billed separately as a repair).
- ☐ Inspect G2258A DLA capillaries and tubings for kinks and damages and replace, if necessary, must be billed separately as a repair.
- ☐ Replace the peristaltic pump cartridge
- ☐ Check that the ALS thermostat unit drain tube is positioned correctly (if applicable)
- ☐ Purge Autosampler and Column Compartment with IPA for 5 min.
- ☐ If the Column Compartment contains a Column Switching Valve, Cap outlet of ALS with blank nut. Otherwise, Cap outlet of

Column Compartment with blanking nut.  
☐ Perform Pressure Test

1. Result  Pass/Fail

2. Result  Pass/Fail

**COLUMN**

**Example Only:**  
 See your originals  
 shipped with the product  
 or handed over by the  
 Customer Engineer

Column Compartment with IPA for 5 minutes. Then Cap outlet of Column Compartment with blanking nut and perform a built-in pressure test.

Result  Pass/Fail

☐ Perform thermostat test.

Result  Pass/Fail

☐ Purge LC System with HPLC – grade water for 10 minutes.

**VALVES**

☐ 1. Record model number

☐ 1. Record serial number

☐ 2. Record model number

☐ 2. Record serial number

☐ 2. Record model number

☐ 2. Record serial number

**G1157A, G1158A G1159A, G1160A**

- ☐ Replace rotor seal and stator face.
- ☐ Inspect valve fittings and capillaries for leaks.

**G1162A, G1163A**

- ☐ Replace rotor seal.
- ☐ Inspect valve fittings and capillaries for leaks.

**DETECTORS**

**G1314B/C – VWD**

☐ Record serial number

- ☐ Inspect flow cell for leaks.
- ☐ Perform Holmium Oxide Test.

Result  <sup>\*</sup> Pass/Fail

<sup>\*</sup> If test fails perform Wavelength Calibration.

☐ Perform intensity test.

Result  Pass/Fail



**Preventive Maintenance Checklist**

**G1315B/C – DAD**

**G1365B/C – MWD**

- ☐ 1. Record model number

\_\_\_\_\_

- ☐ 1. Record serial number

\_\_\_\_\_

- ☐ 2. Record model number

\_\_\_\_\_

- ☐ 2. Record serial number

\_\_\_\_\_

- ☐ Inspect flow cell for leaks  
☐ Perform filter test and attach to checklist  
☐ Perform dark current test

1. Result	<input type="text"/>	Pass/Fail
2. Result	<input type="text"/>	Pass/Fail
3. Result	<input type="text"/>	Pass/Fail

- ☐ Perform Holmium Oxide Test.

1. Result	<input type="text"/>	* Pass/Fail
2. Result	<input type="text"/>	* Pass/Fail
3. Result	<input type="text"/>	* Pass/Fail

- \* If test fails perform Wavelength Calibration.

- ☐ Perform intensity test.

1. Result	<input type="text"/>	Pass/Fail
2. Result	<input type="text"/>	Pass/Fail
3. Result	<input type="text"/>	Pass/Fail

**G1321A FLD**

- ☐ Record serial number

**Example Only:**  
 See your originals  
 shipped with the product  
 or handed over by the  
 Customer Engineer

Intensity	<input type="text"/>	Fail
WL	<input type="text"/>	Excitation
Verif.	<input type="text"/>	Deviation
WL	<input type="text"/>	Emission
Verif.	<input type="text"/>	Deviation

- \* If test fails perform Wavelength Calibration.

**G1362A – RID**

- ☐ Record serial number

- ☐ Check diode balance with pure water in both, the reference and the sample cell, instrument stable as specified

Result  Value

- ☐ Adjust optical balance if value > +/- 0.2

**FRACTION COLLECTORS**

**G1364B/C/D – Fraction Collector**

- ☐ 1. Record model number

\_\_\_\_\_

- ☐ 1. Record serial number

\_\_\_\_\_

Record model number

\_\_\_\_\_

Record serial number

\_\_\_\_\_

Record model number

\_\_\_\_\_

- ☐ 3. Record serial number

\_\_\_\_\_

- ☐ 4. Record model number

\_\_\_\_\_

- ☐ 4. Record serial number

\_\_\_\_\_

- ☐ 1) Replace the inlet / waste tubings  
☐ 2) Replace the valve to needle tubings  
☐ Check that the ALS Thermostat unit drain tube is positioned correctly (if applicable).



## Preventive Maintenance Checklist

### SERVICE REVIEW

- ☐ If a ChemStation is the Instrument Controller, attach printouts of all tests completed to this Preventive Maintenance Checklist.
- ☐ If the Instrument Firmware was updated, complete the IQ attachment protocol and append it to the instrument IQ.
- ☐ Make a test injection of a dilute test mixture (1 drop of Acetone in a 2ml vial of water) with no column.  
\* Use the DETECTOR conditions specified in method OQGRAD.M.
- ☐ Prime system with Customer mobile phase. \* Note – handling of hazardous mobile phase is a Customer responsibility.
- ☐ Record in Instrument Logbook that a PM was performed.
- ☐ Update customer logbooks and EMF sections.
- ☐ Affix the PM Sticker to the 1200 system or Instrument Logbook as specified by the Customer.
- \* If the PM is being performed in advance of an OQPV, use the protocol as guide for Checkout and Setup.
- ☐ Service Order (SO) Number \_\_\_\_\_
- ☐ Date completed \_\_\_\_\_
- ☐ Customer Signature \_\_\_\_\_
- ☐ Support Provider Signature \_\_\_\_\_

**Example Only:**  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer



## Preventive Maintenance Checklist

### Parts Requirements

**Please Note:** Any parts, not included in the parts lists given below, are not part of the recommended Preventive Maintenance Procedure, nor are they included in the price of this service. If a system has a special setup/configuration that requires the use of additional or special parts for the instrument service, then these parts must be ordered separately and billed as a repair. If a customer demands additional service that is not listed in the procedures described above to be performed at his/her instrumentation, then the additional service must be ordered separately and billed as a repair as well as

#### G1310A/11A/12A

This maintenance procedure

#### G1310A/11A Isocratic

2x Seals

#### Purge-Valve Assembly

1x PTFE Frit

1x Outlet Gold seal **5001-3707**

1x Outlet Cap **5042-1346**

#### Outlet Ball Valve Assembly

1x Outlet Gold seal **5001-3707**

1x Outlet Cap **5042-1346**

Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

s of:



## Preventive Maintenance Checklist

### **G1312A Binary Pump kit G1312-68730, consists of:**

4x Seals                      2x **5063-6589** Standard (Pack of 2)

#### **Purge-Valve Assembly**

1x PTFE Frit                **01018-22707** (pack of 5)

1x Outlet Gold seal       **5001-3707**

1x Outlet Cap              **5042-1346**

#### **Outlet Ball Valve Assembly**

2x Outlet Gold seal       **5001-3707**

2x Outlet Cap              **5042-1346**

2x Sieve                    **5063-6505** (pack of 10, needed for binary pump, only)

### **G1310A/11A/12A Isocratic** **consists of:**

2x Wash Seal

2x Wash Seal Gasket

Seal wash items are not included in the kit.  
The kit above is needed for the

### **WASH G1310-68731,**

Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

### **G1361A – Preparation**

This maintenance procedure requires the following consumables **for each pump (the parts are all included in the G1361-68710 Prep. Pump PM kit):**

#### **Pump Head Assembly**

4x Prep Flange Seals     **5022-2188**

#### **Multi-Assy**

1x Filter cup                **3150-0942**

1x SST Filter Assy        **5022-2192**

#### **Seal wash pump**

1x Cartridge                **5042-8507**

1x Tubing                    **0890-1764**

2x Fittings                  **5042-6422**



**Preventive Maintenance Checklist**

**G1376A – Capillary Pump or G2226A – Nano Pump**

This maintenance procedure requires the following consumables:

**Pump Head Assembly**

2x Seals                      **5063-6589** Standard (Pack of 2) or

**Purge-Valve Assembly (if pump is to be used in Normal mode)**

1x PTFE Frit                **01018-22707** (pack of 5)

1x Outlet Gold seal      **5001-3707**

1x Outlet Cap

**Outlet Ball Valve**

2x Sieve

2x Outlet Gold seal

2x Outlet Cap

**Filter Assembly**

1x Frit

Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer



**Preventive Maintenance Checklist**

**G1329A – Autosampler and G2260A Preparative Autosampler**

This maintenance procedure requires the following consumables:

**For G1329A (these parts are all included in the G1313-68730 Autosampler PM kit):**

1x Rotor seal                      **0100-1853** (Vespel®)  
1x Needle Seat  
1x Needle

**For G2260A**

1x Rotor Seal and Stationary  
1x Needle Seat  
1x Needle

**Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer**



**Preventive Maintenance Checklist**

**G1367B Well Plate Sampler, G1377A Micro Well Plate Sampler and G2258A Dual Loop Autosampler**

This maintenance procedure requires the following consumables:

**For G1367B (these parts are all included in the G1367-68730 Wellplate Autosampler PM kit):**

1x Rotor seal	<b>0100-1853</b> (Vespel®)
1x Needle seat	<b>G1367-87101</b>
1x Needle	<b>G1367-87201</b>
1x Peristaltic pump cartridge	<b>5065-4445</b>
1x nut for sample loop fitting	<b>0100-2086</b>

**For G1377A**

1x Rotor seal	<b>0100-2088</b> (Vespel®)
1x Needle seat	<b>G1377-87101</b>
1x Needle	
1x Peristaltic pump	

**For G2258A**

1x Rotor seal	
1x Peristaltic pump	

**Note: If the following needle/seat are lost, they must be replaced SEPARATELY**

1x Needle seat	<b>G2258-87102</b>
1x Needle	<b>G2258-87306</b>
1x Fitting kit 2mm	<b>5065-9950</b>

**Note: After a needle has been replaced several times, the buffer loop capillary will become too short and will also have to be replaced:**

1x buffer loop capillary	<b>G2258-87300</b>
--------------------------	--------------------

**Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer**

**needle is deformed or if  
MUST be BILLED**

**G1328B – Manual Injection Valve and 5065-9922 Prep. Manual Injection Valve**

This maintenance procedure requires the following consumables:

1x Rotor seal	<b>0101-0623</b> (Vespel®) for analytical scale manual injection valve (G1328A/B) or
1x Rotor seal	<b>0101-1233</b> (PEEK®) for preparative scale manual injection valve 5065-9922.



## Preventive Maintenance Checklist

## G1316A – Column Compartment

This maintenance procedure requires the following consumables only if a column-switching valve is installed (G1316A #055 1200 Series 2PS/6PT or G1316A #057 1200 Series 2PS/10PT Valve options):

1x Rotor seal      **0100-1854** (Tefzel®) for valve opt. #055 **or**  
1x Rebuild Kit      **0101-1359** (Rotor Seal and Stator Face) for valve option #057.

## G1157A, G1158A, G1159A, G1160A, G1162A, G1163A - 1200 Series Valves

This maintenance procedure requires the following consumables:

Example Only:  
See your originals  
shipped with the product

**Example Only:**  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

<b><u>Detectors: G131</u></b> <b><u>and G1362A RI</u></b>	or handed over by the Customer Engineer	<b><u>C MWD, G1321A FLD</u></b>
--	--	---------------------------------

The maintenance procedure requires **NO** consumables.

## G1364B/C/D – Fraction Collector

This maintenance procedure requires the following consumables.

Inlet/waste tubing and valve to needle tubing kit  
**G1364-68712** for AS fraction collectors G1364A #050 and G1364C **or** **G1364-68711**  
for PS fraction collectors G1364A or G1364B).

Capillary assembly for G1364D Micro Fraction collector  
**G1364-87304** (25 micro-m ID) **or**  
**G1364-87305** (50 micro-m ID) **or**  
**G1364-87306** (100 micro-m ID).

## **Agilent 1200 Series Liquid Chromatograph Scorp of Work Preventive Maintenance**

## Agilent 1100/1200 Series LC/MSD Quad Major Preventive Maintenance Checklist



## Major Preventive Maintenance Checklist

### Purpose of Procedure

Preventive maintenance is a factory recommended procedure designed to reduce the likelihood of electro-mechanical failures. Failure to perform preventive maintenance may reduce the long term reliability of certain instruments and systems. **Two PM's per year are recommended: the Major PM service will be performed annually with a Interim PM performed 6 months after the Major PM.**

This checklist documents the Major PM service for the Agilent 1100/1200 Series LC/MSD Quad instruments.

### Customer Responsibilities

Customers should ensure that all necessary operating supplies, consumables and usage dependent items such as gases, vials, syringes, calibrant solution and solvents required for the successful preventive maintenance are available.

A customer representative should be available while the preventive maintenance procedure is being performed.

### Important notice for customers

The customer should complete the following before the Support Provider arrives on site:

- ☐ Perform a dual polarity Autotune and retain the printed tune report

### Parts required:

6040-0834	Rough pump fluid, 1L
1535-4970	Mist filter element
BHT-4	Nitrogen gas filter
0100-2051	Inlet filter, 5µm frit
1460-2571	Canted coil spring, qty 1
0100-1855	Rotor seal, Vespel
G1946-60136	Nebulizer needle kit, ES (or G2427A)
G1946-60190	Nebulizer needle kit, APCI (or G2428A)
G1947-20029	Corona needle, qty 1

The following required parts are supplied with the instrument in the shipping kit:

8660-0827	Abrasive cloth, 4000 grit
05980-60051	Lint-free cloth, 1 pk
5080-5400	Cotton swabs, 1 pk
G1946-80054	Cleaning wire, NiCr, 500 ft

### Preventive Maintenance Checklist

- ☐ Discuss any problems the customer is having with the instrument
- ☐ Review customer maintenance records and exclude maintenance on recently serviced items.
- ☐ Review the recent Autotune report. This will give a starting point for evaluating spectral peaks, baseline noise, peak shape, mass assignments and resolution.

### G1956A/B and G1946A/B/C/D

- ☐ Record instrument model no.

- ☐ Record instrument serial no.

**Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer**

- ☐ Inspect vacuum hoses, pump exhaust tubing and power cords for excessive wear
- ☐ Look for any obvious external damage or problems.
- ☐ Note any obvious external damage or problems.

- ☐ Clean air intake on LC/MSD cabinet (inside access door & above the power module).

- ☐ Verify system line voltage meets instrument specifications:

- ☐ Measured voltage: \_\_\_\_\_

- ☐ Drain and replace rough pump fluid (6040-0834).

- ☐ Tighten the four bolts on the rough pump that hold the oil box to the pump body. This will help eliminate rough pump oil leaks.

- ☐ Replace mist filter element (1535-4970).

- ☐ Replace gas filters for nitrogen, (BHT-4).

- ☐ Replace inlet filter assembly 5µm frit, (0100-2051).

- ☐ Replace the rotor seal on the MS selection valve (0100-1855).

- ☐ Remove the desolvation assembly and then remove the glass capillary from the desolvation assembly. Clean the capillary. Follow the ion optics capillary cleaning procedure.

- ☐ Inspect the platinum plated ends of the capillary. Note any physical damage or wear.

- ☐ Remove the ion optics assembly from the ion manifold. Disassemble and clean the ion optics assembly. Follow the documented ion optics cleaning procedure.

- ☐ Remove spray shield, end plate, and capillary cap. Clean the parts.

- ☐ Replace the canted coil spring (1460-2571) in the capillary cap.

- ☐ Reinstall the spray shield, end plate, capillary and capillary cap. Reinstall the ion optics assembly and desolvation assembly.

- ☐ Pump the system down.

- ☐ Record current vacuum readings:

- ☐ Rough Vacuum: \_\_\_\_\_

- ☐ High Vacuum: \_\_\_\_\_



## Major Preventive Maintenance Checklist

- ☐ Verify that all temperatures, pressures, and gas flows reach tune file set points.

### G1948A API-Electrospray Source

Perform source maintenance on currently installed source only.

- ☐ Record serial number

- ☐ Perform general inspection of API-Electrospray source:
  - ☐ Inspect Vented Standoffs for chemical deposits or physical damage.
  - ☐ Inspect nebulizer and needle for physical damage (i.e. dents or corrosion).
  - ☐ Note any obvious external damage or problems.

- ☐ Remove mesh assembly with grey abrasive cloth, followed by a lint-free cloth with methanol. Reinstall mesh.
- ☐ Clean all other interior surfaces of the spray chamber, including the window, with a lint-free cloth with methanol.

- ☐ Replace and properly adjust nebulizer needle (G1946-60136).
- ☐ Verify that all temperatures, pressures, and gas flows reach tune file set points.
- ☐ Check manually that you have tune peaks in positive and negative mode. Generate tune reports in positive and negative mode.

- ☐ Add results to PM documentation.

### G1947A APCI Source

Perform source maintenance on currently installed source only.

- ☐ Record serial number

- ☐ Perform general inspection of APCI source:
  - ☐ Inspect corona needle holder for oxidation or physical damage (i.e. springs on needle holder).
  - ☐ Inspect needle receptacle for oxidation or physical damage (i.e. cracks inside source)
  - ☐ Inspect nebulizer and needle for physical damage (i.e. damaged tip or corrosion).
  - ☐ Note any obvious external damage or problems.

- ☐ Replace the APCI corona needle (G1947-20029).

**Example Only:**  
See your originals shipped with the product or handed over by the Customer Engineer

- ☐ Verify that all temperatures, pressures, and gas flows reach tune file set points.
- ☐ Check manually that you have tune peaks in positive and negative mode. Generate tune reports in positive and negative mode.
- ☐ Add results to PM documentation.

### G1971A APPI Source

Perform source maintenance on currently installed source only.

- ☐ Record serial number

- ☐ Perform general inspection of APPI source:
  - ☐ Inspect nebulizer and needle for

physical damage (i.e. damaged tip or corrosion).

- ☐ Note any obvious external damage or problems.

- ☐ Allow the source to cool completely.
- ☐ Clean the lamp window with a lint-free cloth and methanol.
- ☐ Check that lamp lights. **Note:** Replacement of the APPI lamp is not covered during the PM procedure.
- ☐ Replace and properly adjust nebulizer needle (G1946-60190).
- ☐ Using the grey abrasive cloth, abrasively clean the bottom of the vaporizer can, and then wipe with a lint-free cloth with methanol.

Clean all other interior surfaces of the spray chamber, including the window, with a lint-free cloth with methanol.

Verify that all temperatures, pressures, and gas flows reach tune file set points.

- ☐ Check manually that you have tune peaks in positive and negative mode. Generate tune reports in positive and negative mode.
- ☐ Add results to PM documentation.

### G1978A Multimode Source

Perform source maintenance on currently installed source only.

- ☐ Record serial number

- ☐ Perform general inspection:
  - ☐ Inspect corona needle holder for oxidation or physical damage (i.e. springs on needle holder).
  - ☐ Inspect needle receptacle for oxidation or physical damage (i.e. cracks inside source)

**Major Preventive Maintenance Checklist**

- |   |   |
|---|---|
| <input type="radio"/> Inspect nebulizer and needle for physical damage (i.e. damaged tip or corrosion).         | <input type="checkbox"/> Service Order (SO) Number _____  |
| <input type="radio"/> Note any obvious external damage or problems.   | <input type="checkbox"/> Date completed _____             |
| <hr/>   |   |
| <input type="checkbox"/> Replace the APCI corona needle (G1947-20029).  | <input type="checkbox"/> Customer Signature _____         |
| <input type="checkbox"/> Replace and properly adjust the nebulizer needle (G1946-60136).                        | <input type="checkbox"/> Support Provider Signature _____ |
| <input type="checkbox"/> Clean all other interior spray chamber, including with a lint-free cloth w             |   |
| <input type="checkbox"/> Verify that all temperat pressures, and gas flow file set points.                      |   |
| <input type="checkbox"/> Check manually that yo peaks in positive and ne Generate tune reports in negative mode |   |
| <input type="checkbox"/> Add results to PM documentation.   |   |

**Example Only:**  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

**Service Review**

- ☐ Record in Instrument Logbook that a Major PM was performed.
- ☐ Affix the PM Sticker to the 1100/1200 LC/MSD Quad system or in the customer logbook as specified by the Customer.

**Note:** The purpose of generating tune reports after planned maintenance is to verify that the system is functional in positive and negative modes. Autotune should NOT be performed at this time.

- ☐ An Autotune should be run after the system has been allowed to thermally equilibrate for at least 11 hours following a system vent. During this time, it is not unusual for the instrument to exhibit mass assignment shifts, poor peak shapes and/or poor resolution.

## **Agilent 1100/1200 Series LC/MSD Quad Major Interim Preventive Maintenance Checklist**



## Interim Preventive Maintenance Checklist

### Purpose of Procedure

Preventive maintenance is a factory recommended procedure designed to reduce the likelihood of electro-mechanical failures. Failure to perform preventive maintenance may reduce the long term reliability of certain instruments and systems. **Two PM's per year are recommended, the Major PM service will be performed annually with a Interim PM performed 6 months after the Major PM.**

This checklist documents the Interim PM service for the Agilent 1100/1200 Series LC/MSD Quad instruments.

### Customer Responsibilities

Customers should ensure that all operating supplies, consumables and dependent items such as gases, vials, syringes, calibrant solution and so required for the successful preventive maintenance are available. A customer representative should be available while the preventive maintenance procedure is being performed.

### Important notice for customers

The customer should complete the following before the Support Provider arrives on site:

- ☐ Perform a dual polarity Autotune and retain the printed tune report

### Parts required:

6040-0834 Rough pump fluid, 1L

### Preventive Maintenance Checklist

- ☐ Discuss any problems the customer is having with the instrument
- ☐ Review customer maintenance records and exclude maintenance on recently serviced items.
- ☐ Review the recent Autotune report. This will give a starting point for evaluating spectral peaks, baseline noise, peak shape, mass assignments and resolution.

### G1956A/B and G1946A/B/C/D

- ☐ Record instrument model no.  
\_\_\_\_\_
- ☐ Record instrument serial no.  
\_\_\_\_\_
- ☐ Record current vacuum readings:
  - ☐ Rough Vacuum: \_\_\_\_\_
  - ☐ High Vacuum: \_\_\_\_\_
- ☐ Check manually that you have tune peaks in positive and negative mode.
- ☐ Vent the instrument.

- ☐ Check manually that you have tune peaks in positive and negative mode. Generate tune reports in positive and negative mode.

- ☐ Add results to PM documentation.

### Service Review

- ☐ Record in the Instrument Logbook that an Interim PM was performed.
- ☐ Affix the PM Sticker to the 1100/1200 LC/MSD Quad system or in the customer logbook as specified by the Customer.

**Note:** The purpose of generating tune reports for preventive maintenance is to verify that the system is functional in positive and negative modes. Autotune should NOT be performed at this time.

Autotune should be run after the system has been allowed to thermally stabilize for at least 11 hours following a system vent. During this time it is not unusual for the system to exhibit mass assignment errors, poor peak shapes and/or poor resolution.

**Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer**

- ☐ Verify system line voltage meets instrument specifications:
  - ☐ Measured voltage: \_\_\_\_\_
- ☐ Drain and replace rough pump fluid (6040-0834).

- ☐ Tighten the four bolts on the rough pump that hold the oil box to the pump body. This will help eliminate rough pump oil leaks.

- ☐ Pump the system down.

- ☐ Record current vacuum readings:
  - ☐ Rough Vacuum: \_\_\_\_\_
  - ☐ High Vacuum: \_\_\_\_\_

- ☐ Verify that all temperatures, pressures, and gas flows reach tune file set points.

- ☐ Service Order (SO) Number  
\_\_\_\_\_

- ☐ Date completed  
\_\_\_\_\_

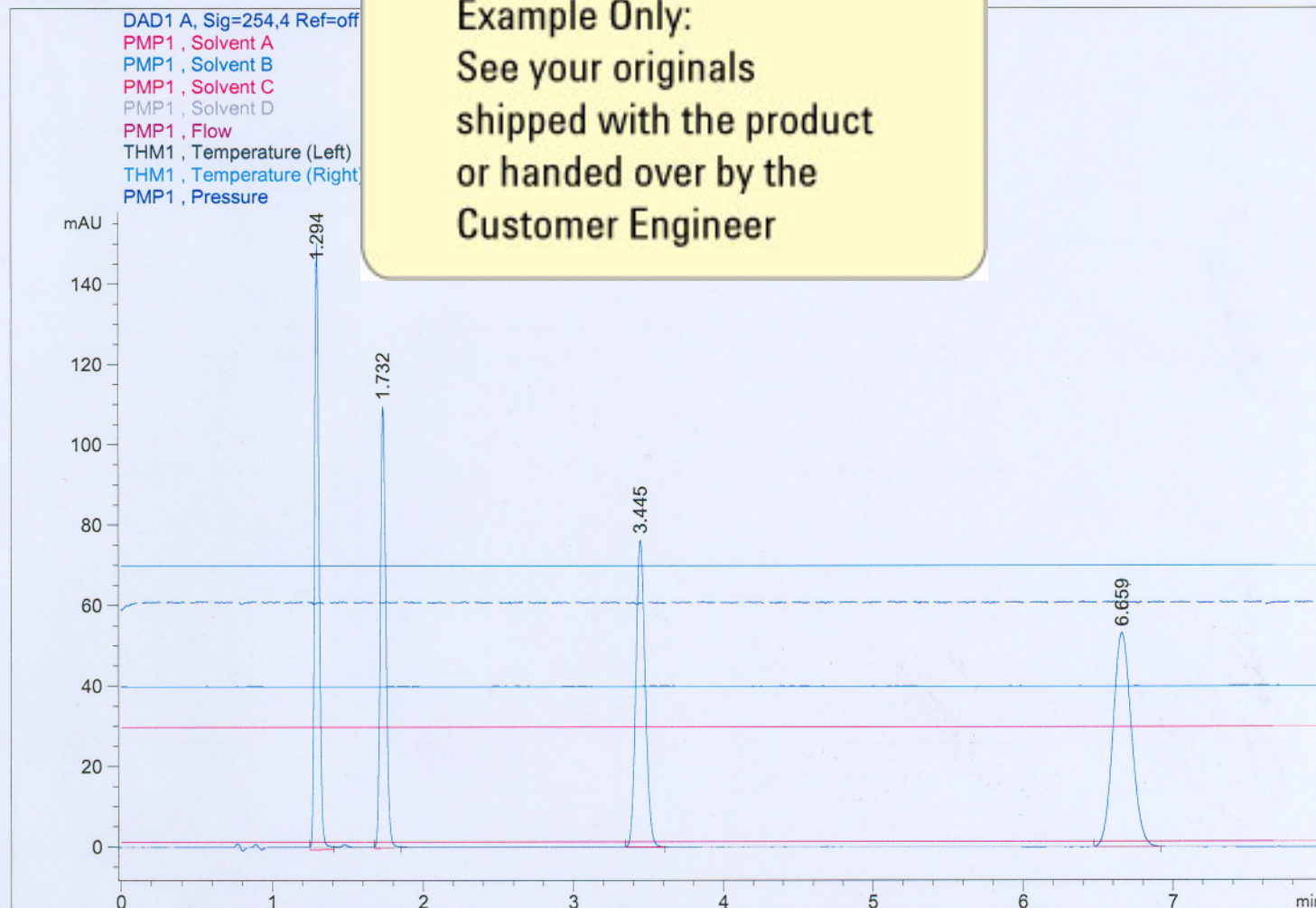
- ☐ Customer Signature  
\_\_\_\_\_

- ☐ Support Provider Signature  
\_\_\_\_\_

## System performance and noise

```
Sample Info      : sample : Isocratic standard sample
                  DAD       : slit 2nm/all in peak spectra - DAD-UV - 40 C
                  method    : isocra.m 30% Water 70% ACN
```

**Example Only:**  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer



Area Percent Report with Performance and Noise

Calib. Data Modified : Friday, February 24, 2006 4:58:12 PM

Multiplier : 1.0000  
Dilution : 1.0000  
Use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=254,4 Ref=off

Noise determination:

Time range		Noise	Noise	Noise	Wander	Drift
from	to	(6*SD)	(PtoP)	(ASTM)		
[min]	[min]	[mAU]	[mAU]	[mAU]	[mAU]	[mAU/h]
0.000	0.500	6.525e-2	4.739e-2	-	-	2.975
2.000	3.000	8.137e-2	6.124e-2	-	-	-1.377
4.000	6.000	7.300e-2	7.030e-2	2.405e-2	3.869e-2	-1.738

RetTime	k'	Area	Height	Symm.	Width	Plates	Resol	Signal
[min]		[mAU*s]						
1.294	0.15	309.39569						7.2
1.732	0.53	279.87131						0.3
3.445	2.05	332.17877						9.0
6.659	4.89	459.16510						0.7

Example Only:  
See your originals  
shipped with the product  
or handed over by the  
Customer Engineer

**5 Performance Qualification (PQ) Phase**  
Customer contributed material

## Customer contributed material

## 5 Performance Qualification (PQ) Phase

### Customer contributed material



## **In This Book**

This Qualification Workbook for the AGILENT TECHNOLOGIES 1200 Series systems and modules for LC contains documents of the 4 phases of the entire instrument life in a user's laboratory:

- Design Qualification (DQ),
- Installation Qualification (IQ),
- Operational Qualification (OQ),
- Performance Qualification (PQ).

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